S. HRG. 101-107

CHEMICALS AND FOOD CROPS

HEARING

BEFORE THE

SUBCOMMITTEE ON TOXIC SUBSTANCES,
ENVIRONMENTAL OVERSIGHT,
RESEARCH AND DEVELOPMENT

OF THE

COMMITTEE ON
ENVIRONMENT AND PUBLIC WORKS
UNITED STATES SENATE

ONE HUNDRED FIRST CONGRESS

FIRST SESSION

MAY 15, 1989

Printed for the use of the
Committee on Environment and Public Works

U.S. GOVERNMENT PRINTING OFFICE

99-690 WASHINGTON : 1989

For sale by the Superintendent of Documents, Congressional Sales Office
U.S. Government Printing Office, Washington, DC 20402

S321-23

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CHEMICALS AND FOOD CROPS

MONDAY, MAY 15, 1989

U.S. SENATE,
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS,
SUBCOMMITTEE ON TOXIC SUBSTANCES, ENVIRONMENTAL OVERSIGHT, RESEARCH AND DEVELOPMENT,
Washington, DC.

The committee met, pursuant to notice, at 9:40 a.m., in room 406, Dirksen Senate Office Building, Hon. Harry Reid [chairman of the subcommittee] presiding.

Present: Senators Reid, Lieberman, and Warner.

OPENING STATEMENT OF HON. HARRY REID, U.S. SENATOR FROM THE STATE OF NEVADA

Senator REID. Good morning. The Subcommittee on Toxic Substances, Environmental Oversight, Research and Development is meeting today to review the regulatory framework in place to address the safe use of chemicals on foods. The subcommittee will also consider the potential health consequences of dietary exposure to neurotoxic substances and the carcinogenic risks of pesticides in general and fungicides in particular.

Some pesticides accumulate in or on food as residues and may ultimately be harmful to human health. Headlines across the country have brought to light the possible environmental and health dangers posed by pesticides. In dollars and cents, the annual environmental and health cost of using agricultural chemicals could be as high as $2 billion.

Since biblical times the apple has been one of our more famous fruits, often mentioned throughout literature. "Keep me as the apple of the eye" is found in the Old Testament and is often used to describe something precious. When a plan or charted course of action is changed, we often refer to "upsetting the apple cart."

Apples have been thought to quench the flames of Venus, keep the doctor away, and blamed for bringing in the evils of the world. Many proverbs refer specifically to the "rotten apple." According to Benjamin Franklin, "The rotten apple spoils his companions." Some could compare this 1736 proverb found in Poor Richard's Almanac to the attention focused on Alar and the apple industry.

The CBS news program "60 Minutes" highlighted a report issued by the Natural Resources Defense Council entitled "Intolerable Risk: Pesticides in our Children's Food," which concluded that preschoolers are being exposed to dangerous levels of toxic pesticides in fruits and vegetables which can cause cancer, neurological damage, and other health problems. The NRDC report states that

the Environmental Protection Agency underestimated the risks of daminozide, a pesticide used on apples to prevent pre-harvest fruit drop, increase storage life, and promote red color. Daminozide, also known as Alar, breaks down into UDMH, a component of rocket fuel, which may be carcinogenic.

Infants and children eat proportionately far greater amounts of vegetables, and especially fruits, than adults. Because children eat more apples and apple products, NRDC calculates the risk of daminozide as 240 times greater than the risk acceptable by EPA.

The Alar controversy is just the tip of the iceberg. Maneb and mancozeb are part of a group of chemicals known as EBCDs, used to prevent fungus and bacteria on vegetables. These two fungicides are necessary to grow fruits and vegetables in areas with high humidity and warm temperatures. An EPA analysis has determined that both chemicals are carcinogenic.

The American consumer is alarmed about the alphabet soup of chemicals found on common fruits and vegetables. In spite of repeated assurances by industry, scientific societies and Federal officials, the American consumer is leery of the safety of the foods we eat. Part of the public's mistrust can be attributed to the regulatory process governing pesticide use and food safety.

Insecticides, herbicides, fungicides, rodenticides, fumigants and disinfectants are pesticides. These chemicals are very important to agriculture and industry in the effective control of a variety of pests. Agricultural chemicals account for a significant portion of the U.S. economy.

Forty thousand to 50,000 pesticide products are in use in the United States today. According to the EPA, approximately 1.2 billion pounds of pesticides, costing $65 billion, are sold each year. That's almost five pounds of pesticides for every man, woman, and child in this country. Seventy percent of all pesticides in this country are applied in agricultural production. Agricultural chemical exports have also increased dramatically in the last decade.

No one can argue the benefits derived from the use of pesticide products. The United States is the envy of the world in agricultural production. However, we have not achieved this enviable position without cost.

Since the end of World War II, the use of pesticides in agricultural production has increased dramatically. Ironically, crop losses from insects have nearly doubled during the same period, according to the U.S. Department of Agriculture. This phenomenon is attributed to many things, not the least of which is the immunity developed because of the increased use of pesticides. These same chemicals also kill natural predators.

The Federal Insecticide, Fungicide and Rodenticide Act, known as FIFRA, was enacted in 1947 to protect farmers by assuring that marketed pesticides were effective for their stated purpose. The act was not to protect the consumer of these products. Subsequent amendment of FIFRA has concentrated on the health and environmental safety issues of pesticide use.

The Federal Food, Drug, and Cosmetic Act is the primary food safety statute and is administered by the Food and Drug Administration. EPA, however, is responsible for setting pesticide residue levels of tolerances. A tolerance is the maximum legal limit of pes-

ticide residue allowed to remain in or on raw agricultural commodities, processed foods or animal feed.

The public's concern about the risks from pesticide residues—and its ultimate avoidance of some of these products—has also sparked concern among those involved in the production of our abundant food supply. The public's concern is seen in the recent dramatic decreases in the purchases of apples.

This hearing will attempt to sort out many of these questions. The witnesses will present testimony about the statutes governing pesticide use and food safety; the existing regulatory process potential health risks posed by pesticides and possible alternatives.

I would like to turn the time to Senator Warner for a statement, if he has one.

Senator WARNER. I'll yield to my colleague.

Senator REID. Senator Lieberman has spent a great deal of time on this subject, and I am very appreciative of that. Senator, do you have a statement?

OPENING STATEMENT OF HON. JOSEPH I. LIEBERMAN, U.S. SENATOR FROM THE STATE OF CONNECTICUT

Senator LIEBERMAN. Yes, thank you, Mr. Chairman and Senator Warner. I want to thank you, Mr. Chairman, particularly for the leadership that you've shown in convening this hearing on the subject of how Government regulates pesticides in our food supply.

This issue is obviously very much on the minds of many Americans who share our belief that it is Government's obligation to do all it can to protect the consuming public from chemicals which can cause harm.

We all know that there is no such thing as a risk-free world. In an open society we're free to take many risks. Some people smoke knowing that it may lead to disease. Some ride in cars without fastening a seat belt, fully aware that if an accident happens they're going to be more vulnerable. All manner of human endeavor carries risk.

Most risks we take by choice. Other risks, however, are forced upon us. It is the nature of those risks that I think concerns us here in this hearing today.

The American people know that they cannot avoid all risk in eating food, but at the very least they want to be as fully informed as possible about the nature of the risks that they are taking. Fatty meat and fried food may be bad for us, but we know that, and if we choose to eat it, it's a risk that we're aware of and we take intentionally.

But what makes many people angry is when we find out that we're exposed to dangerous chemicals on our food that the Government knew about years ago but did little or nothing to eliminate those chemicals or even warn us about them.

The fact is that the Government first became aware that Alar, which is used on apples, as you know, could cause cancer as early as 1973. Yet, here we are 16 years later and Alar is still an approved pesticide.

Now we learn that the EPA staff wanted to ban Alar back in 1985, but the EPA Scientific Advisory Panel told the EPA to go slow, to go back and do another study.

It takes a report on television to focus public attention on the issue, but the Government, unfortunately, after that report and after the NRDC report, minimizes the threat once again, saying that only 5 percent of the apples had Alar on them.

It is the job of this committee to look over the shoulder of Government to make sure it's doing its job. This is an oversight committee.

So, under your leadership, Senator Reid, we've looked into the issue a little further, and we found that the Scientific Advisory Panel, which is supposed to render an independent judgment on the safety of chemicals on our food supply, is in fact loaded with chemical industry consultants.

Seven out of eight members of the SAP, the Scientific Advisory Panel, that stopped the move to ban Alar in 1985 worked for the chemical industry at the same time they were on the panel. One of the seven even went on to do consulting work for Uniroyal, the company that makes Alar, just a few months after leaving the Scientific Advisory Panel. In fact, he swung right through the revolving door and showed up at a meeting at EPA speaking in favor of Alar working for Uniroyal.

Another member of the Scientific Advisory Panel that kept Alar on the market left the panel and was hired by a fruit growers association to testify in favor of another chemical made by the manufacturer of Alar, a chemical which, incidentally, he had also given the okay to when he was a member of the Scientific Advisory Panel.

The famous 5 percent figure that the EPA hung its hat on in proclaiming the safety of apples turns out, apparently, to be wrong. Even the EPA has now backed off that original claim, upping its figure to 15 percent, and the latest statement 15 percent, not just of apples, but of apple growers; the number of apples could obviously be larger.

I have no reason to believe that even the new figure is the accurate one. In fact, most outside analysts say that more like 30 percent of the apples have Alar on them; some studies have shown more than 50 percent have Alar on them in this year's crop.

Mr. Chairman, the American people are willing to live with risk, but at least let's tell them the consistent truth about the risk they face and let them make up their own minds. Who can blame average citizens for being skeptical about Government reassurances when reassurances are based on elusive figures?

How can we believe that the food on our table is genuinely free of chemical risk when the people in Government who tell us that, or at least tell our Government not to tell us to stop using Alar, have food on their table courtesy of the industry that manufactures those chemicals?

I have a one-year old child who until this scare broke out ate a lot of applesauce and drank a lot of apple juice. I'm upset about the way Government did not inform me earlier as one consumer, as one parent, about the danger of this product to children. I'm con-

cerned about the way Government went about regulating or not regulating this process.

Ultimately, we're talking here not just about the nutritional value of food; we're talking about the ethical values of Government and the process by which those values are worked out.

Alar is very much on everybody's mind today, Mr. Chairman, but I know that you intend in this hearing to get underneath the story of the day to the process that we have which is supposed to protect us and our families from chemicals in the food supply, to see how it's worked, and to see how we can make it better.

Thank you, Mr. Chairman.

Senator REID. Senator Warner.

OPENING STATEMENT OF HON. JOHN W. WARNER, U.S. SENATOR FROM THE COMMONWEALTH OF VIRGINIA

Senator WARNER. Mr. Chairman, I'll be brief. It appears to me this is a time for action and not speeches.

Here we are about to indict Government for its failure. Well, part of that Government is the Congress of the United States. If there's been a difficulty out here for 16 years, then the pendulum points in our direction as well as in the direction of the Executive branch.

If this law is deficient, why didn't we, in our oversight capacity, remedy that deficiency? I think there's enough blame to go around in several directions. In the meantime, we do, indeed, have young people. Many of us are concerned about the ability to consume our food in a safe manner.

We also have an infrastructure that provides that food and has been working diligently within the framework of the laws and the regulations provided in large measure by the Congress.

Today I hope, in fairness, we give the opportunity for that infrastructure to express the difficulties it has faced with this law.

So I conclude that, while there's blame to be leveled, it may well in large part be directed toward the Congress.

Senator REID. Thank you, Senator Warner.

We have received word this morning that Jim Hightower, the Commissioner of Agriculture from the State of Texas is unavoidably going to be absent today. So I would like to ask Ralph Nader and S. Mason Carbaugh to come forward now. We'll hear first from Ralph Nader.

So there will be sufficient time for questions, we would ask you two gentlemen and the rest of the scheduled witnesses to limit your oral statements to five minutes. Your written statements will be included in the record in full.

I have, Mr. Nader, reviewed your statement in its entirety. So if you could summarize that for the subcommittee, it would be appreciated.

Senator WARNER. Mr. Chairman, I join you in welcoming this panel. I've worked with them over many, many years in a variety of capacities. Mr. Nader and I worked for a long time on the subject of air bags in automobiles. Indeed, the goals that we charted some seven or eight years ago are finally coming into being.

Commissioner Carbaugh and I have marched through many a corn field and wheat field and dairy and orchard in the Commonwealth of Virginia. I can speak unequivocally as to his knowledge about the agribusiness industry and the people who try to labor long and hard to make it work.

We welcome you.

Senator REID. Could both of you raise your right hands?

[Witnesses sworn.]

Senator REID. Mr. Nader, would you proceed?

STATEMENT OF RALPH NADER, ACCOMPANIED BY RICK HIND, U.S. PUBLIC INTEREST RESEARCH GROUP

Mr. NADER. Thank you, Mr. Chairman and members of the subcommittee.

With me today is Rick Hind who works on pesticides for the U.S. Public Interest Research Group.

I would like to make a few points and submit my testimony for the record.

The recommendations on legislative improvement start on page 11 and go through the following page. I won't repeat them, but they are quite specific and I hope the subcommittee will give them adequate consideration.

The first point to make is that since the 1940s the use of pesticides in terms of volume has increased by tenfold and the loss to our crops has increased in percentage terms as well. There have been various estimates, and I hope the subcommittee can nail this down more precisely, but there have been many estimates that the tenfold increase in volume has been accompanied by almost a double increase in percentage loss to the crop. Even if it's not an increase, it does give us pause about the kind of treadmill that agricultural chemicals have placed the economy on.

What is happening is that the insects are mutating at an accelerating pace. Where they once would take five years to mutate into a resistant strain, scientists are finding that mutation is occurring in less than two years.

The Colorado beetle has resisted almost anything thrown at it, and the chemical companies are placed in a position of having to constantly remodify their pesticides into more virulent formulas in order to keep up with the resistance of the mutational pattern.

Secondly, we hear consistently from farm sources as well as environmental groups that the chemical companies are pushing overapplication of these pesticides. Obviously, they make more money by selling more volume. There is an incentive to try to encourage farmers to overapply in terms of volume per acre.

We know, of course, that workers are exceptionally exposed to these chemicals; that groundwater has been contaminated, as pointed out in my testimony at the bottom of page 8 referring to an EPA study on groundwater contamination.

Thirdly, we know that many of these agricultural chemicals are used for cosmetic purposes. I think the subcommittee would do the public an important service to nail this down more precisely. Alar, for example, makes the apples rosier red. There are many applications post-harvest to our crops for primarily cosmetic purposes. The

consumers do pay a penalty for that perfect, blemish-free fruit that they see in the supermarkets for sale. Obviously, the use of chemicals for cosmetic purposes entails a much greater rigor even by the most reticent regulator.

Fourth, I think we should move toward a standard of protecting the public which is the standard of infant and child protection. That should be the standard, not the average adult. The average infant and child are consuming more of some of these products per body weight such as apples and apple products by far than adults.

The onset of the chemical age in agriculture really started after World War II. So, if, indeed, there is a long incubation period for carcinogens, we may be seeing that incubation period produce more victims because people over 40 grew up in a period in our country of very, very reduced pesticide exposure compared to the Americans who grew up in the fifties and sixties.

I think also we need to emphasize it is not just cancer; it is not just carcinogens, mutagens, tertragenic effects; it's also neurotoxic and other chronic effects which you will be hearing about today, and I'm pleased that you're requesting testimony on that score.

Fifth, I think we need to look at the system in terms of how it screens out pesticides. For those who denigrate the impact of pesticides as we now are exposed to them, we should note the following: that the research and development in this area are accelerating and, if the system is not in place to screen out pesticides of what some might think were relatively minor risks, are they going to be in place, to screen out some very, very virulent chemicals that may be coming down the road with high velocity mass distribution impact.

Furthermore, if we don't do this job properly, we will not be encouraging the move to alternative chemical-free agriculture, whether in research or actual farm application, as rapidly as we should.

The pesticide laws are based on tolerance levels involving average adult consumption of foods like watermelon or other products which are obviously absurd. That's like saying to someone, "You can cross this river safely, friend, because it has an average depth of 3 feet."

When they put a tolerance level on your eating 7.5 ounces of cantaloupe a year—that's the average adult consumption—obviously, that does not cover a very significant percentage of our population.

In the auto safety area, they work on percentiles; that certain standards have to protect 95 or 98 percent of the motorists in terms of body size. I think there needs to be something of that incorporated in tolerance levels.

Finally, I think the most exciting new private development to curtail hazardous unnecessary pesticide use involves the growing demand by consumers in supermarkets to have the supermarket chains test the fruits and vegetables and other products through independent laboratories.

Two and a half years ago I called up the chairman of Safeway, Mr. McGowan, and asked him to issue a statement assuring the customers of Safeway all over the country that Safeway will not buy Alar-treated apples or apple products. That statement was issued in a press release a few days later, and other supermarkets followed.

Those chains also received certifications of non-Alar use by their growers. As it turns out, these certifications were not verified independently by the large supermarket chains through independent laboratories, but it did give us an idea of how powerful a tool consumers have by pressing their supermarkets and conferring with supermarket managers who then report to their headquarters which, in turn, leverages the power of the big buyer, the supermarket chain, through independent lab tests for safer food.

I might add that Raleys Supermarket, 57 stores in the Sacramento, California area, started this about two years ago with independent laboratory testing, notifying their customers in full page newspaper ads, and other supermarket chains have begun to do this in Washington State and Southern California.

In addition to the proper regulatory reforms, I think we should indicate how important it is to have information given to consumers so they can feed back to supermarkets.

Thank you very much.

Senator REID. If you would remain there, we'll have some questions for you, Mr. Nader.

Mr. Carbaugh.

STATEMENT OF S. MASON CARBAUGH, COMMISSIONER OF AGRICULTURE AND CONSUMER SERVICES, COMMONWEALTH OF VIRGINIA

Mr. CARBAUGH. Thank you very much, Senator Reid, Senator Warner, Senator Lieberman.

I appreciate very much the opportunity to come at Senator Warner's invitation. Likewise, I have a great deal of respect for our good Senator from Virginia.

I am Commissioner of Agriculture and Consumer Services in the State of Virginia, a post which I have held for 17 years now. I've been very lucky.

I'll try to summarize my statement as much as I can. I will read parts of it and summarize the rest of it.

While recent public opinion and attitude with respect to current farm management techniques might give rise to food safety concerns, it is my belief that American consumers have access to the safest, most wholesome, and diverse food supply at a lower cost per capita than any other consumers in the world.

Now with that, let me come to what the State, at least the State of Virginia, has done, is doing, and plans to do relating to pesticides, because I think that is a piece of the puzzle in terms of the kinds of things that this committee is concerned.

Our original pesticide law was passed in 1948, a year after the Federal act, and for the same purpose primarily, and that was to deal with product; in other words to ensure that what was on the label was in the package and that it would do what they said it would do.

When FIFRA was amended then in the early seventies, our focus shifted from product to proper use of pesticides. Virginia's law was amended in 1975 to track the Federal legislation.

At that time we began issuing certificates and licenses to private and commercial applicators and entered into cooperative agreements with EPA for the enforcement of that act.

We have had a long history of involvement with pesticide management programs in Virginia. Several recent events required us to examine our role to see if improvements to program management and statutes were needed.

I have provided you with a result of the study, conducted on pesticide management in Virginia. I hope that, if you haven't, you might look at that. It was a much-accelerated study, but I think the product is a respectable product.

We did find some weaknesses in Virginia's legislation. We moved to try to shore that up. We looked at program administration and funding, registration of pesticides, licensing of businesses, training and certification of technicians, enforcement, and so forth.

I would like to dwell, if I might, on what we did. In the 1989 session of the Virginia General Assembly, we passed a new bill, a much amended bill. The new bill does contain some of the old language of the former legislation, but it has changed quite a lot.

The one point I want to make to you folks is that that new law, as major a revision as it was, passed both houses of our general assembly without a dissenting vote. Now I doubt if you could get that done in the Congress of the United States, but I do give credit to the general assembly of Virginia because I think it was an indication that there was a commitment by all to be responsive to pesticide management issues in the State.

We had a couple of problems come up. We had two people who died as a result of a misapplication down at Galax, a very tragic, unfortunate incident.

So, as a result, we've got a new pesticide law in Virginia. We've created a new 11-member pesticide control board. That board will have the full responsibility, policy responsibility, for all pesticide programs in the State, dealing with the licensing of businesses that manufacture, store, sell, mix, or recommend for use or apply pesticides; registration of pesticides, as was the case, has been the case; requiring reporting and recordkeeping; establishing improved, strengthened training and testing standards for commercial applicators; and providing for a two tiered system, with registered technicians, which the Federal act does allow, and we've moved in that direction; and also changes in requirements for private applicators.

The Act strengthens the means by which the board can deal with violators, considerably changed. We will establish a fee structure to defray the cost of the program. We, of course, have been and will continue to classify and subclassify areas of certification.

We have established an annual business license. One of the problems is that we didn't know what was being sold, where it was being sold. We do in broad terms, but not how much—and distribution and storage. Requiring a business license will give us a better handle on the distribution and use of pesticides.

Previously, commercial applicators were only licensed if they applied restricted use pesticides. Commercial applicators now will have to be licensed now if they apply any pesticide. You have to be certified, I mean to say, if they apply any pesticide, regardless of whether it's a general use or restricted use.

As I pointed out, we've got a two-tiered system now, which means everybody has to meet some level of competency in the application of pesticides.

We've considerably strengthened, added more options for enforcement, and imposition of civil penalties. Civil penalties range from a minimum of $1,000 to a maximum of $100,000, depending on the severity of the violation.

Evidence of financial responsibility has been increased. We now have a maximum of $200,000 surety bond or liability insurance. That was changed to a minimum of $200,000 bond or liability insurance.

The governor recommended and the general assembly appropriated almost $800,000, $788,000, to add additional people for the purpose of enforcement.

It's my belief that, once all the provisions of the act are fully implemented, all the findings and recommendations contained in the study will be operational. Further, once implemented, Virginia will have one of the strongest pesticide management programs in the country.

We've worked with EPA, I think, and continue to work with them. We have a good working relationship. I think we need to continue to work to improve that relationship.

On page 7 there is an error down in the last paragraph where it says, "Washington Association of State Departments of Agriculture;" that should be "National Association of State Departments of Agriculture," if you would change that. Our national association does work with EPA on a number of issues.

I want to just mention Alar because you mentioned it and others mentioned it. I want to tell you what we've done. We've been testing apples, I guess, for pesticides since the early thirties. We do field tests every year. This year was no exception, but when the Alar situation came out we implemented a special testing program.

We sampled 125 lots of fresh apples and apple products. Included in there were eight samples for the school lunch program. That was enough because of the way they purchase those and we distribute them.

There were no detectable levels of Alar found in any of the school lunch samples. Ninety-one percent of the remaining samples were Alar-free. Positive samples showed trace amounts ranging from 1 part per million to a maximum of 2.8 parts per million.

I think that represents to me, at least in Virginia, and I think it's representative some of the U.S. food supply that it continues to be one of the safest in the world.

Well, we have a lot of work to do, and I know a lot of times it's a continuing challenge and cannot be accomplished by one individual, by one group, or by one level of Government. I think it has to be accomplished by all of us working together in a cooperative fashion.

You also have been provided a copy of our new pesticide act.

Mr. Chairman, I appreciate the opportunity to be here.

Senator REID. This is to advise the members of the subcommittee that we will hold ourselves to the 5-minute rule for questioning and, if necessary, come around for a second round of questions.

Mr. Carbaugh, you add to the quandary that we find ourselves in with this Alar thing. First the EPA says that about 5 percent of the apples contain Alar; then they come back and say, well, it's 15 percent. We have other independent agencies that say that it's much higher than that, around 40 percent.

Before you include the whole United States in your Virginia sample, you need some more information, because I think, based upon the information that's now before the public, simply no one's going to believe that.

Senator WARNER. Mr. Chairman, I think he was relating only to Virginia figures——

Senator REID. No, he said it's representative of the United States.

Senator WARNER. We're not here to sell Virginia apples today; we're trying to present the problem.

Mr. CARBAUGH. I don't mind selling a few Virginia apples, Senator.

Senator WARNER. I understand that.

Senator REID. Senator Warner, I would be happy if he had left it to selling Virginia apples, but when he tried to sell the apples from the State of Washington and other places, I have some concern with that.

Mr. CARBAUGH. I don't mean to make it representative of everything in the United States, but there are a lot of apples out there, varieties of apples on which Alar has never been used.

Senator REID. One of the reasons, among others, that we're having this hearing is to determine how much Alar is used and on what.

Mr. Nader, I first became interested in the subject of eating foods containing pesticides as a result of a television program that my wife watched where a book, with which I think you're familiar because you wrote the introduction to it, called "Eating Clean" was discussed. You're familiar with that.

I think with a lot of what we learn, we learn from our family. In this instance—and I speak, I think, for a lot of people throughout the country—that this Alar situation is of concern to people, families. My family bought two big batches of apples like we always do and they haven't been eaten this past two weeks because people are concerned. That's too bad because, as Senator Warner indicated, this isn't a one-man show. A lot of people have caused this concern.

Separate and apart from that brief statement, there are a number of things in your written statement that I think need, at least as far as I'm concerned, some elaboration. DDT, which was supposedly banned 17 years ago, it's my understanding is still found in the milk of mothers that are breast feeding; is that right?

Mr. NADER. Yes.

Senator REID. How do you account for that? Is it because pesticides don't disappear that easily?

Mr. NADER. That and also the ingredients in DDT, although they're not called DDT, some of them are used in other pesticide formulations.

Senator REID. What about imported food? From the work that you have done, what is there to protect us from the pesticides on imported foods?

Mr. NADER. Not much. I think the testimony refers to surveys that the—surveillance on pesticides coming in on imported food is about as close to zero as you can get, although with the more recent Chilean grape situation, they may have stiffened it a bit.

In our country we have a system of law which allows pesticides, that are illegal to be sold in this country, to be sold abroad. They are used on coffee, bananas, other crops, vegetables in Mexico.

Senator REID. Produced in the United States?

Mr. NADER. Pesticides produced in the United States, and they're coming back into our country with these residues.

NRDC, about five years ago, using the most sophisticated testing methods on coffee, could not find a sample that did not have an illegal residue on it. Some of these pesticides are also produced by license in these countries and applied to crops in those countries and exported back into the United States. That's what some have called the vicious circle of poison.

Senator REID. Another, I think, startling bit of testimony that you have given in your written statement pertains to another area that this subcommittee is addressing, that is, composite materials and safety in the workplace. We've held some hearings and Senator Warner has participated in those.

One of the things that we're concerned about is that we have 65,000 chemicals that are used in America today, but yet we've only tested a few of those and we haven't tested any mixing them together.

You've indicated in your statement,

> In this regard, the agency also fails to calculate the required data on the cumulative effects of exposure to food use pesticides likely to be used and found together.

The example given is lung cancer and cigarette smoking. If you smoke cigarettes, the danger to asbestos exposure is much greater.

What do you feel is available, if anything, regarding the cumulative effect of these pesticides?

Mr. NADER. Very little. EPA really has its hands full in trying to test a fraction of the active ingredients in pesticides. They really haven't gotten around to multiple carcinogenic impacts as well as synergistic impacts.

These are very challenging missions for the EPA and they are operated under a pesticide law which I have called years ago a "no law" law, a very poorly-drafted law, a politically-loophole-ridden law. Then you combine that with the drumbeat of lobbying by the chemical industry on EPA and an administration in the eighties that didn't believe in regulation, and you say, well, to what extent are they looking for multiple impacts or synergistic impacts? That's like way down the pike in terms of the EPA and the burdens it has in just testing one ingredient or one pesticide at a time.

I am glad you pointed that out because that is the hidden part of the pesticide iceberg that escapes some of the facile dismissals by some observers of the risks of chemical pesticides in our society—just as the yardstick of the infant being the measure of the safety of any pesticide has so long been ignored, just as the actual intake of food by millions of Americans instead of an average tolerance level has been so long avoided.

I'm glad this subcommittee is looking into these issues which really represent the looming risks that we have to face very shortly.

Senator REID. Senator Warner.

Senator WARNER. Thank you, Mr. Chairman.

Mr. Nader, as I mentioned earlier, we have had our battles together when we have been on the same side and we've been on opposite sides, and I'm not sure which side we're on this time; it's too early to tell.

We've got a job here in the Congress to work with the Executive branch with the help of people like yourself to try to reframe these laws. That's going to take a little time.

You're a survivor and a battle-scarred veteran of a lot of public policies debate. I think you've survived because there is an element of fairness and credibility attached to your work, and we want to avoid scare tactics, but they're present in this case.

It's almost like a roller-coaster. As young families watch this TV program, they don't know whether to feed their children apples or not. There are farmers out there trying to do the best they can, relying on information promulgated by the Federal Government, the State government, the county agents. There are grocers trying to deal with this problem.

Let's try to make a few simple statements here this morning so that people can be guided by what we're trying to do. The bottom line question, if a housewife approached you this morning and said, "Mr. Nader, can I feed my children an apple or give them juice," what would be your reply?

Mr. NADER. I would tell her to buy the apple juice that has been certified to be Alar-free, and there are brand names now which have been certified to be Alar-free.

Second, I would tell her that peeling the apple won't do any good because Alar is systemic.

Thirdly, I would tell her never feed your child anything, any product in excess, no matter what it is. Have a very diverse——

Senator WARNER. By that, you mean a balanced diet, once or twice a week?

Mr. NADER. Yes.

Senator WARNER. When it comes to the fresh fruit, how do we deal with this problem? I know some grocers are endeavoring to put out a notice that it's Alar-free.

Mr. NADER. Well, that begins to be a fair, truthful advertising issue. When Safeway announced two and a half years ago it was not going to sell you any Alar-treated apple products, they relied on the certifications in writing of the growers, and they sent me copies of them. But they didn't rely on their own independent sample lab tests, which they should have. If a small supermarket chain in Sacramento could do it, certainly Safeway could do it.

I think right now the Congress really should pay attention to increasing health claims in the food industry, especially where they now are assuring people that these products—this fruit, this vegetable—are chemical-free or Alar-free.

They could be, and the question is——

Senator WARNER. So are you suggesting that the major distributors initiate their own testing program and we'll just have to rely for the time being on that until Congress acts?

Mr. NADER. Yes, and I'm sure the Federal Trade Commission would have a role there, too. It then becomes a deceptive advertising question: can they back up their assurance?

Senator WARNER. We're getting back into all the laws and regulations. Let's talk about the next 30, 60, 90, and very often it's 120 days before Congress finally acts. We're trying to help those people, not only the consumers, but the growers and the handlers of this fruit.

So your first thought is, if it's marked on the juice bottle or the container, give it a chance. With fresh fruit, you're urging that the distributors do their own testing and put up their own statement of facts associated with that fruit.

Mr. Carbaugh, how would you deal with those questions?

Mr. NADER. I might add also, except for systemic chemicals on food, it does pay to wash them very carefully in the kitchen.

Mr. CARBAUGH. Well, we do at the State level, as I indicated, and have been for a number of years, continually sampling and testing in our laboratories anything that's in the marketplace. We make the results of that information available. Admittedly, it's not a universal sampling program. We, obviously, don't sample everything, but we do sample enough to know what's out there in the marketplace and simply try to educate people.

We have occasionally halted sales. I don't know whether we have recently, but we can stop sale on a product that exceeds the limits and take it off the market. That is an action that we have taken over the years, but it doesn't happen regularly.

Senator WARNER. Are you able to quantify the number of States that are on a level with the Commonwealth of Virginia? In other words, I think we're out on the cutting edge in the forefront of this battle, whereas some of the other States are falling behind.

Is there any way of——

Mr. CARBAUGH. Well, I wouldn't want to leap out that far this morning, Senator, but I think we—and I don't have that specific information with me, but I think we do have at least a reading on what the situation is in other States.

Senator WARNER. Well, other States are aware of what we're doing in the Commonwealth of Virginia.

Mr. CARBAUGH. Yes, sir.

Senator WARNER. I have a small apple orchard and I know something about the business, and I find that down in my area of Virginia when this problem began to surface there was a lot of volunteer activity, quite apart from the State and the Federal activity, on the part of the farmers and the cooperatives to begin to try to deal with this problem themselves.

Would you like to tell us a little bit about that?

Mr. CARBAUGH. You're talking about the application of Alar and that type of thing?

Senator WARNER. That's correct.

Mr. CARBAUGH. I can tell you that most of the growers—I wouldn't want to say 100 percent, but most of the growers took pretty seriously when the processors, particularly back a couple of

years ago in 1986, said: "We're not going to buy your apples if you use Alar."

I know that they quit using Alar, large numbers of them did, because if you can't sell your product there is not much use in producing it. The processors have the capability of testing those apples and do test those apples.

I think that they actually put into practice what the marketplace was demanding. Farmers are pretty sensitive really to the marketability of their product.

What happens is that they get caught on occasions like this, through no fault of their own really, and they just can't take it back. I think it's unfortunate that they've been hurt like they've been hurt this last couple of months. It's a real serious economic problem for them.

Senator WARNER. By and large, farmers are independent business men and women trying to make an honest living, and I know that in our State, and I think elsewhere, when this problem began to surface several years ago, there were a lot of voluntary standards imposed to stop the use of Alar and other pesticides.

I thank the panel.

Senator REID. Senator Lieberman.

Senator LIEBERMAN. Thank you, Mr. Chairman.

If I may just for a moment continue with what was being said here, as I've gone through this story, it does seem to me that there is a way in which the apple growers themselves have been victimized. We're at an incredible situation now where the apple growers are demanding that the manufacturer of Alar stop selling it—no answer there that I've heard. In a sense, the apple growers are demanding that EPA ban it immediately, but EPA starts a process that could take as long as three or four years. It makes you wonder.

Mr. Nader, welcome. As the Senator from Connecticut, your home State, I'm glad to welcome you again.

I know that your prepared testimony has some recommendations for us. If you could for this part of the hearing, if we asked you to redesign the current governmental system of protecting the food supply from hazardous chemicals, what are the main three or four elements of that program that you'd advise us to adopt?

Mr. NADER. First of all, I think they should move toward a health-based standard for determining which chemicals should be allowed on the market.

Senator LIEBERMAN. Talk about that a little bit because I don't think we understand that.

Mr. NADER. Once you operate on a cost-benefit standard, you inject an enormously amorphous political element in the calculation because when you're talking about the cost, are you talking about the cost to consumers or are you talking about the cost to industry? Usually it's the cost to industry.

Senator LIEBERMAN. In other words, EPA could now determine that a particular chemical is bad for our health but still keep it on the market because it would be disruptive, have a negative cost for presumably the industry; is that correct?

Mr. NADER. Yes; right. And, of course, costs can be vastly inflated, as they have been in a number of industries trying to challenge proposed safety regulations.

Secondly, I think before you do anything, you've got to test. The testing programs have to have measures against which they are tested. EPA is understaffed, under-authorized, and under-willed, so to speak, to do the job.

That's why the first thing Congress really has to do is in the legislation, rather than delegating it to regulatory discretion, put in an infant-child-based standard and put very strict controls on discretion in terms of what average tolerance levels should be based on by way of food consumption and to require that the tests include the kinds of metabolites that are often much more virulent.

Alar is far less of a hazard than the metabolite of Alar when apples are cooked to be turned to apple sauce or apple juice.

I might add that in the fungicide area this is a very, very serious problem. That has to be focused on.

I think EPA also should have a much more candid and fulsome information program to consumers so they can begin to be more alert and push from the retail sector of the marketplace vis-a-vis the supermarket chains and then have the supermarket chains represent consumer health interests in the food area, and not simply buy from the growers willy-nilly based on cost and appearance of the produce and sell it to the consumers without independent testing.

Senator LIEBERMAN. What kind of information would you want EPA to provide to consumers?

Mr. NADER. Information requiring supermarkets to post the kind of chemicals that are used in the various products, so people can go into supermarkets, and they can ask routinely the manager or the clerk for a printout of what is used.

The whole focus on apples now is Alar. Imagine if people knew how many dozens of other chemicals are used on apples and what their purpose is. That should be part of a pamphlet or a printout coming to the consumer who wants that information.

I think also it's important to always give the purpose of the chemical application: what is it really for? More people are going to be upset, rightly so, and I think they'll begin to realize that their aesthetic pleasure is being purchased at a risk to their health if they think these chemicals are used largely for cosmetic purposes.

Pesticides that have been banned for use on food should have their tolerances revoked. Heptachlor is a good example of where the EPA has failed to do this in a timely fashion.

The same is true for manufacturers of pesticides. They should not be allowed to continue their registration or food tolerance unless they have provided EPA and FDA with practical methods of monitoring for these pesticides.

There's often a large lag time between the time they get it registered and the time they file, if they ever do, practical methods for monitoring their pesticides.

Senator LIEBERMAN. Let me ask you one final question. To go back to your first point, would you want to see a system where,

once any risk to health was found in a pesticide, that it would be pulled off the market?

Mr. NADER. It depends on what the risk is. We all know the detection systems are becoming more and more precise, and it's inescapably going to be a judgment call, but it should be one that is established in written form so that it can be reviewed and monitored. That's important.

I am very strong on a health-based standard. I'm very strong on not seeing the loss of one life just for some economic advantage.

But let's take an example—that one life will be lost 2,000 years from now through impact on the genetic inheritance. It's a judgment call. Even that kind of prediction is notoriously judgmental.

So we should never confuse quantitative numbers with precision in this area. We should come down very hard, though, on the wildly inflated economic costs that are attributed.

We all remember when vinyl chloride was detected to cause liver cancer. The chemical industry said it would cost thousands of jobs and billions of dollars, and it was controlled, and it didn't do anything of the sort. In fact, it made the chemical companies more efficient in terms of a byproduct of controlling vinyl chloride. So we should be very concerned about that.

I might also add that Congress should be definitive in banning the export of banned and unregistered pesticides. If it's unsafe for Americans, it should be unsafe for Brazilians and unsafe for American consumers coming back into this country with contaminated coffee or bananas.

Senator LIEBERMAN. Okay, thanks. My time is up.

Senator REID. Especially when we wind up eating it by importing it.

Mr. Carbaugh, you indicated that a particular incident led to Virginia's review of its pesticides program. Can you describe this incident in more detail for the panel?

Mr. CARBAUGH. Yes, it was actually, I guess, two incidents that brought it to a head. One had to do with a fraud situation where people were bilked out of huge sums of money by a fraudulent commercial pesticide applicator, and our law didn't provide us the means to deal with fraud; it had to be dealt with civil statutes, not under the pesticide law. The changes will correct that.

The other incident had to do with a fumigation of a house for wood borers over in Galax where the people re-entered. Proper testing was not done before allowing re-entry, and the people reentered and spent the night in the house and then succumbed later after inhaling fumes.

Those were the two incidents that really caused the whole issue to be studied. Our law was not strong enough really to deal with those two incidents like they should have been.

Senator REID. The statements of Ralph Nader and Commissioner Carbaugh will be made part of the record in addition to the new law that is in effect in the State of Virginia. (See pp. 71 and 84.)

Senator Warner, do you have more questions?

Senator WARNER. No, thank you.

Senator REID. Senator Lieberman?

Senator LIEBERMAN. May I just add one more thing?

Senator REID. Of course.

Senator LIEBERMAN. I think attention should be brought to the exciting development of commercially-viable organic agriculture and what's going on all over the country among farmers who are seeing the handwriting on the wall.

The USDA, certainly having put many, many millions of dollars into research and development on behalf of the chemical pesticide industry, should encourage more demonstration projects, research, and grants to promote more widespread application of low-input farming techniques.

In your State of Virginia a former Foreign Agricultural Service officer of USDA has been marketing directly and by license beef products without any artificial chemical use, whether nitrogen fertilizer or other chemicals. Many of you have eaten Garnett beef in some of the fanciest restaurants in Washington, D.C.

To preclude any ambiguity, I do want to emphasize my continuing support for the Delaney clause that is administered by the FDA.

Senator WARNER. If I could have one further quick question for our witness.

As I look at this legislative process, and having been a part of it now in my 11th year, I'm not so sure how quickly Congress can grapple with this tough question, but it looks like the judgment has been leveled on Alar.

I'm going to ask both of you this simple question: what Congress can do one day it can undo the next. We could simply pass a law tomorrow unilaterally banning Alar and put that one behind us; in the meantime, go on with our legislative process and grind out a solution.

Mr. Carbaugh, would you recommend that course of action?

Mr. CARBAUGH. No, let me answer that, I don't think that's a wise course, sir. I think what I would like to see——

Senator WARNER. It could be 18 months if we let the regulatory process under the current framework grind on. Then if they exercise their perfect right to go into court, that could be prolonged.

Mr. CARBAUGH. If there is an imminent hazard, that's one thing. If there's not been proven to be a hazard—I'll tell you one thing: we can sometimes focus on these residue issues with food, and my experts and food people keep telling me, and I believe them, that one of the greater risks is the microbiological risk in food and food handling.

I just say to you, don't focus too strong on all the residue issues when there's just as much risk in food with the microbiological issues.

Senator WARNER. We're getting far afield of where I want to go here. My point is that, if we just banned it, then it would bring back a measure of confidence to the consumer, particularly the housewife struggling with all the problems raising children.

There are other products that haven't been mentioned here which use a form of Alar that also are very much involved in the daily lifestyle of many young people. My point is if we just swiftly went out and stopped that, at least we could bring a measure of confidence back into the marketplace. I think most of the producers have stopped using Alar anyway.

What I think we need is some swift, decisive action to restore consumer confidence in the marketplace, in at least apples and several other products that's worrying me.

Mr. Nader.

Mr. NADER. I agree. Alar and its metabolite are among the more potent carcinogens regulated by the EPA. The apple industry, the apple growers themselves have asked Uniroyal to take Alar off the market. Many apple growers have told me that apples can be grown without Alar. Indeed, I recall a time in our history when they were.

Senator WARNER. I know that to be a fact.

Mr. NADER. For Congress to send a multiple signal that it is deadly serious about deadly pesticides, it should ban Alar and its metabolite by name by legislation immediately.

Senator WARNER. I don't like to take this type of unilateral action, but I'll consult with my chairman and others members to see whether or not we regard this as a pragmatic solution to a difficult problem. This is like wrestling with an octopus, all this pesticide issue, but we've got to do it. But I'm concerned with the time within which we do it, we may be jeopardizing not only the health, but also the marketability of certain products which seriously affects small farmers and producers and the like.

Mr. NADER. There's a convergence now between the growers' and farmers' interest and the consumers' interest. Uniroyal is singularly isolated on this subject now.

Senator REID. Senator Lieberman.

Senator LIEBERMAN. Thank you, Mr. Chairman.

Let me just say, Senator Warner, picking up from what you just said, that I'd be proud to cosponsor such an action with you, and I say that, in the first place, to send a clear signal that the Congress is concerned about the presence of chemicals in the food supply; secondly, to restore some confidence in the midst of all the confusion and anxiety that exists among the consumers. Third, in my opinion, it is justified by the facts. As Mr. Nader just said, we're not just talking about a chemical that happened to be picked out by NRCD or "60 Minutes." This is one of the more potent carcinogens that they've been testing.

One of the studies that I saw showed that the risk for adults was 1 in 1,000 and the risk for infants was even higher, 1 in 100.

Senator REID. Senator Lieberman, that would sure speed up the regulatory process.

Senator LIEBERMAN. Yes, it would.

Commissioner Carbaugh, if I may just ask you a few questions about the new law, because I think it may lead the way perhaps for us in Congress as we get over this immediate problem and deal with all the other chemicals and the whole process of regulation.

Do I understand correctly that under Virginia's new law that pesticides have to be licensed before they can be used in the State?

Mr. CARBAUGH. Businesses have to be licensed. Those who store or sell or distribute pesticides will have to have a business license.

Senator LIEBERMAN. I see. So that you're not doing a State regulation of individual pesticides?

Mr. CARBAUGH. Commercial—well, yes, we are.

Senator LIEBERMAN. Yes?

Mr. CARBAUGH. They will be registered. It's just a difference in terminology. We call that registration of product—we've been doing that since 1948. We will continue to do that.

What the new law does, is allow the new board to take into consideration whether there are any adverse effects on health or environment as it relates to Virginia.

Senator LIEBERMAN. Of a particular pesticide?

Mr. CARBAUGH. Of a particular pesticide, yes.

Senator LIEBERMAN. And, do I understand that in coming to that finding that the burden is on the commercial applicator or on the manufacturer to prove the safety?

Mr. CARBAUGH. That's right.

Senator LIEBERMAN. And that would include so-called old pesticides as well as new pesticides?

Mr. CARBAUGH. It could. We, I guess, have that bridge yet to cross, but it could.

Senator LIEBERMAN. And the question of safety is not just for the workers, but for the consumers of products on which that pesticide is placed?

Mr. CARBAUGH. That's correct.

Senator LIEBERMAN. Okay, I appreciate your answers because that may suggest some trend or direction in which we might move as we alter the Federal system.

Thank you. I have no further questions.

Senator REID. Thank you very much, gentlemen.

Mr. Hind, we appreciate your being here also and recognize your contribution to this whole area.

The people that will be on our next panel will be Dr. Charles Benbrook from the National Research Council and Mr. Peter Guerrero from the General Accounting Office.

Gentlemen, would you, while you're there, raise your right hands and be sworn?

[Whereupon, the witnesses were sworn.]

Senator REID. Dr. Benbrook, would you proceed, please? We'd ask that you'd summarize your statement because the written statement is more than the five minutes allotted.

STATEMENT OF CHARLES M. BENBROOK, EXECUTIVE DIRECTOR, BOARD ON AGRICULTURE, THE NATIONAL RESEARCH COUNCIL

Mr. BENBROOK. Yes, Mr. Chairman, I'd be delighted to.

I'm Charles Benbrook, the executive director of the Board on Agriculture, in the National Research Council.

Over the years we've conducted a number of studies on pesticide regulatory issues, the science of pest control. One of our studies, released in 1987, I hope the Senators have seen. It was entitled, "Regulating Pesticides in Food, the Delaney Paradox." This is the report that documented the dimensions of the problem that has now erupted into a full-scale national issue and led to these hearings.

What I would like to try to do today is trace with you what's wrong with our Federal statutes governing pesticide regulation and point you in the direction of where some legislative and administrative solutions might be found.

I'd very much like to try to help you understand the dilemma that EPA finds itself in. We are embarking down a course in this country which I think is very inefficient in dealing with this problem. I think it's important to understand its dimensions.

The problem that EPA faces in regulating cancer-causing chemicals is that it must deal with two statutes. One statute, the Food, Drug and Cosmetic Act, includes the infamous Delaney clause. The Delaney clause applies to certain pesticide tolerances and would impose a zero risk standard for cancer risk from any residues on foods.

This Food, Drug and Cosmetic Act Delaney clause applies only in cases when a pesticide residue concentrates on processed foods and when the pesticide has been shown to be an oncogen. Our report documented and analyzed the frequency of this instance in the food supply and tried to understand how EPA can reconcile this zero risk standard in the Food, Drug and Cosmetic Act with the risk-benefit standard in the FIFRA statute which governs the registration of pesticides and the establishment of tolerances in raw foods.

The dilemma that EPA faces is that one statute tells it to do one thing and another statute in certain instances tells it to do something else. It's really placed in a position of having to break one law or another.

Dr. Moore, later this morning in his testimony, will no doubt explain to you what the agency has tried to do to reconcile these conflicting standards.

But, ultimately, for the Nation to regain control over the safety of its food supply in a reasonably efficient regulatory process, fundamental inconsistencies between these two statutes have to be resolved; the fundamental conflicts between the FDA and the EPA have to be resolved, and some common sense has to be restored to the pesticide regulatory process.

I'd like to go directly, if I may, to the major findings of our report because I think they are helpful in putting into perspective the dimensions of this problem.

EPA has set about 8,500 distinct tolerances for the use of a pesticide on an individual crop. That is sort of the universe of food uses of pesticides that have to be evaluated for their risks and benefits.

About 80 percent of the total estimated worst case oncogenic risk stems from residues in fresh foods and about 20 percent from processed foods. One category of pesticides, used principally for the control of plant diseases, fungicides, accounts for over half of the risk in fresh fruits and vegetables, and almost 80 percent of the risk in processed foods.

Let me have a chart put up now that's drawn from our report, if I could, right here. I'd like to walk the panel through some of this information through use of this chart.

This is a table drawn directly from this report. It contains a list of many of the common active ingredients that have a number of food use registrations. The first column of numbers has the number of food uses or tolerances. You'll see 83, 83, 50 uses. One is down at 11; benemyl is up at 101. Obviously, these chemicals are registered for use on a wide range of crops.

You'll note that these chemicals are ranked according to the total estimated risk, the worst-case risk, if they were used on all crops and if residues appeared at the tolerance level.

Now you'll also notice that, of the top ten, all of them are fungicides except for one insecticide. You'll also notice that several of them have received a weight-of-the-evidence ranking by EPA for human carcinogenicity of B2, which means that EPA considers these to be probable human carcinogens.

A "C" ranking indicates that there is some evidence of carcinogenicity in humans, but it's certainly not as firm or convincing as in the case of the B2 ranking.

You'll also note here the year of the first tolerance, which is a good indicator of the year of introduction or how old the chemicals are. Our top ten, 1955, 55, 57, 78—the most modern of the newer chemicals—62, 55, 61, 67, 72, 55, on and on and on.

Mr. Chairman, we have an old chemical problem when we talk about pesticide risk in the food supply. If EPA is going to do anything serious to reduce risks in the diet, they can draw a line right here and forget everything else. This is where the risk is. It so overwhelms the risks from all other pesticides that, if they don't deal with these, they will have virtually no impact on risk in the food supply. This is what our report documents.

The distribution of risk in the food supply is not even. We have 8,500 tolerances, and a handful of them account for virtually all the risk. EPA has, to the extent that we can detect a carcinogenic potential of a pesticide, to the extent that we can measure these things, EPA has a pretty good idea of where that risk is.

The problem is it doesn't have a statute that allows it to go directly to those risky uses of chemicals and take action to reduce the risk. Alar is a perfect case in point. Captan is a perfect case in point.

If this problem is to be resolved, the limitations in the statute that make it very difficult for EPA to take actions to reduce risk—perhaps not to zero, but substantially reduce it—must be dealt with.

Mr. Chairman, my time is up. I'll be glad to respond to any questions.

Senator REID. Mr. Guerrero.

STATEMENT OF PETER F. GUERRERO, ASSOCIATE DIRECTOR, ENVIRONMENTAL PROTECTION ISSUES, RESOURCES, COMMUNITY, AND ECONOMIC DEVELOPMENT DIVISION, GENERAL ACCOUNTING OFFICE

Mr. GUERRERO. Thank you, Mr. Chairman and members of the subcommittee.

Rachel Carson in "Silent Spring" said, "if we are going to live so intimately with these chemicals, eating and drinking them, taking them into the very marrow of our bones, we had better know something about their nature and their power."

Since her words in 1960, our production of pesticides has increased fivefold. Recognizing that, indeed, we did need to know more about these substances, EPA undertook, beginning in 1972, a program to reassess existing pesticides and their tolerances. This

program is called the re-registration program, and that's what I'll be discussing this morning.

Three years ago we reported on EPA's lack of progress in carrying out this re-registration program. We concluded that EPA was proceeding at a pace that would take it into the next century to complete the process.

In recognition that speeding up the process could help restore the public confidence, Congress in 1988, as you know, refocused EPA's assessment program by shifting some of the burdens for re-registering pesticides to industry, by providing additional and more certain funding for the program, and by setting deadlines for accomplishing this task.

Our follow-up work to date shows that EPA has made some progress in gathering data on existing pesticides, especially major food-use pesticides, but it is still at a preliminary stage in assessing the risks of other older pesticides.

EPA has not completed assessments for any of the 822 pesticides subject to re-registration. In addition, due to gaps in knowledge about the toxicity and exposure of most pesticides used on foods, EPA has been able to completely reassess the safety of pesticide residues on food for only four of approximately three hundred eighty-seven food use pesticides.

Mr. Chairman, today I will describe the magnitude of this task facing EPA and will also talk about the progress that has been made since we issued our 1986 report. Secondly, I'll discuss some unresolved issues that we feel will affect the success of this program.

As you know, most pesticides were registered and most pesticide tolerances were established with much less data than is now required. This has resulted in the need to re-register these products and re-evaluate their tolerances according to current data requirements and current scientific standards.

This reassessment of existing pesticides accounts for more recent concerns about the potential health effects such as cancer and also adverse ecological and environmental effects. This is, indeed, a formidable task for both EPA and the pesticide industry.

To accomplish this, EPA must review industry-submitted health and environmental studies, make regulatory decisions on the risks and benefits of those pesticides, and most of them, as you know, have been registered over the last four decades.

Industry must conduct the required tests. Some of these tests take up to four years to perform. In the interim, previously registered pesticide products may be sold and distributed under their existing registrations.

The Congress, through the FIFRA amendments last year, significantly refocused this program. In our transition report to the Congress on EPA, we noted that it would take extraordinary leadership on the part of EPA to complete this new congressional mandate because EPA had not been successful in the past in meeting deadlines or implementing pesticide reforms.

We have two charts with us today that depict EPA's progress in reregistering pesticides and in reassessing pesticide tolerances on foods. We believe these charts will help the Congress monitor EPA's progress in implementing the new amendments.

Mr. Chairman, if I may direct you to the first chart, I will cover the status of pesticides undergoing re-registration today. Line 1 shows that there are approximately 1,300 active ingredients used in pesticide products that are subject to re-registration.

Line 2 shows that the number of active ingredients, which are grouped by EPA in what they call "cases", number 822. These cases contain active ingredients with similar chemical characteristics. However, the exact number of active ingredient cases that will be subject to re-registration will not be known until October of this year.

Line 3 shows that EPA has issued 194 interim registration standards. These standards are interim because EPA lacked sufficient information to fully assess these pesticides and their tolerances at the time the standards were developed. This list represents most of the major food-use pesticides.

Line 4 shows that EPA has completed 18 second-round reviews which EPA had previously called final registration standards. Most of the second-round reviews have identified a number of new data gaps, and EPA has had to postpone re-registration decisions on products containing the active ingredients until additional data are received and reviewed.

Line 5, Mr. Chairman, represents the bottom line results of our efforts to update our 1986 report at your request. A review of the 18 second-round pesticides indicates that EPA lacks sufficient data to completely reassess the risks associated with any of these 18 pesticides.

That updates the information we have on the status of pesticides undergoing re-registration.

Mr. Chairman, our second report on the status of EPA's reassessment of tolerances for food-use pesticides shows similar limited results. The bottom line here is that EPA has completed all tolerance actions for only three of four pesticides and that EPA has a long way to go.

I would like to close by briefly describing a number of unresolved issues that we would like to bring to your attention that we feel further complicate the re-registration process for EPA.

First, developing a final assessment on active ingredients does not complete re-registration. EPA will have to take and apply decisions reached on each of these active ingredients to some 35,000 or more individual pesticide products containing the active ingredients. Currently, there is not a clear plan to do that.

Secondly, EPA will need to have some procedure and strategy for keeping those registrations current in the light of the fact that pesticide uses change; the formation of pesticides change over time; there are advancements in science and technology; there's introduction of new data of the type that had not been previously identified, such as neurotoxicity data that we talked about earlier this morning in the hearing. In this area as well, EPA's plan for implementing FIFRA 1988 does not specify how these registrations will be kept current.

Finally, EPA needs to enforce label requirements and restrictions that have been imposed by way of these interim standards. These labeling requirements are a very important tool for identify-

ing to both the user and consumer of these pesticide products how to use them safely.

EPA has informed us that they have not generally pursued cancellation actions for failure to comply with the interim status labeling requirements because they feel that cancellation procedures under FIFRA section 6 are cumbersome and time-consuming.

In summary, Mr. Chairman, despite progress, EPA is still at a preliminary stage in assessing the risks of older pesticides. FIFRA 1988 will help accelerate the formidable task, but does not resolve all the pesticide regulatory issues. Because EPA has not been successful in meeting deadlines or implementing pesticide reforms in the past, extraordinary leadership is needed to meet this challenge.

Thank you.

Senator REID. Mr. Benbrook, in the chart that you showed us and the testimony that you gave, you indicated that there were approximately 10 or 12 of these pesticides that create 80 or 90 percent of the problem. What if EPA were to cancel these approximately 10 chemicals on this chart? How would the risk to which we are exposed be reduced?

Mr. BENBROOK. To the extent that we can measure risk and to the extent the scientific tools available are accurate, it would eliminate a very large portion of the risk. This particular table does not include daminozide and it would need to be among the products impacted by such a cancellation.

But, Mr. Chairman, I caution to add that EPA has to follow the law that it's in charge of administering and that it (cancelling all uses of 10 pesticides) would be in an extraordinary accomplishment or task, if you will, for the agency to come forth with risk-benefit findings that will withstand the inevitable court challenges that would come if it were to move simultaneously against essentially 90 percent of the fungicide use in American agriculture, because that would leave virtually no crop protection tools for very major industries, particularly if it were done very rapidly.

Senator REID. But, Dr. Benbrook, as we've heard from the other panelists, there are new pesticides being brought into the marketplace on a frequent basis. Wouldn't you think, as indicated in the chart that you have here, that the scientific community could come up with something that's new? These things are old. Some of them are 30-odd years old.

Mr. BENBROOK. That's correct, but one of the parts of our report that was not read as carefully as the risk estimates, delved into the likelihood and rate of new pesticide introductions, and also where the pesticide industry is investing most heavily its R&D dollars. On both counts, the fungicide area or plant disease area comes up substantially wanting. There are relatively few effective new fungicides in field-scale testing, and it's very difficult, frankly, to find a chemical that has activity against a lot of these diseases.

In the case of herbicides, and often the case of insecticides, there are very economical, practical, proven alternatives to some of the herbicides and insecticides that appear at the top end of this list. But in the case of fungicides, there simply are not alternatives in some areas. That is why EPA has been so slow and deliberate in trying to think through what it should do in the case of fungicides, because several of these fungicides are substitutes for many of the

uses. If it were to cancel one, the growers would simply switch to another. There obviously would not be any great degree of risk reduction.

EPA is trying to deal with having to render final regulatory judgments on eight or nine major products with several hundred food uses basically all at once. The recent Captan decision is a first step, an EBDC decision is due at any time.

I think that it is very important that EPA be given an opportunity to do this in a thoughtful way or there will be considerably greater costs imposed on all of our society than probably necessary to achieve a fairly high degree of risk reduction.

Senator REID. Dr. Benbrook, do the current laws hinder replacement of older, very risky pesticides with the newer, safer pesticides?

Mr. BENBROOK. Yes, they do. They do so because a new pesticide, to get on the market, the first thing that has to happen is a tolerance has to be set. A pesticide registration can't be granted without a tolerance in place, nor can a pesticide registration that's on the market be cancelled without that tolerance being revoked. The tolerance and the registration action are linked.

What happens under current EPA policy is that new chemicals that come into the tolerance process and registration process have to have very up-to-date data and are subjected to a very strict standard. Any indications of oncogenicity generally are enough to stop a chemical from being registered.

Whereas for perhaps the very same use, there could be an older product on the market with a 1 in 10,000 risk, but because there is no alternative, no registered alternative for the chemical, its benefits are very high.

The Delaney clause standard and the strict requirements of a complete data set stop safer alternatives from coming to the market. Yet, EPA, because it has to live within the risk-benefit standard of the FIFRA act, can't cancel the old products because there are no benefits. If that isn't a Rube Goldberg situation, I've never heard of it.

Senator REID. And isn't that a problem we have with the consumer? The consumer looks at this and, in effect, throws up his hands. I guess what I'm saying is, you indicated that the EPA—and I'm sure Mr. Moore, who is here representing the EPA today, understands that we're going to be asking him some tough questions—but isn't that one of the problems we have relative to EPA? We have waited all this time and you're saying we should wait longer. Maybe EPA and the Executive branch of Government and Congress must streamline the process.

Mr. BENBROOK. I think there is a way to move swiftly and dramatically, but also responsibly. I can understand the Senator's frustration about Alar and your determination to go to the floor this afternoon and pass a bill to cancel it. You'll only be 10 days behind the Iowa legislature, by the way, which did pass a bill in Iowa banning Alar. So the thought has occurred to other political leaders, but that's really not dealing in a responsible manner with the pesticide risks in the American food supply.

Banning Alar is not going to solve the pesticide food safety problem. It's not just Alar; it's a statute that allows the situation to go on and on and on.

Now if you're going to go to the floor and pass a law that deals with the top 12, then you'll have a substantial impact on the safety of the food supply, but that's a very much more complicated task. Congresses in the past have been humbled by the difficulty of dealing with regulatory matters of this complexity through legislation and have tried to give regulatory agencies the tools to get the job done.

What I, and all the people who worked on this report and have been dealing with these issues for several years, hope for is that the current level of concern and interest in the subject will create enough pressure, if you will, to resolve some of the underlying problems of the statute, and then the pesticide regulatory process can begin to work, not just for fungicides on new crops, but for herbicides in groundwater, insecticides, applicator exposure and farm worker exposure.

Alar is not the only pesticide regulatory problem that we have in this country—it's just the one that's captured national attention. We've got to get to a situation where it doesn't require a "60 Minutes" episode to get EPA to cancel a pesticide. That's ridiculous.

Senator REID. You've rendered great service to the Congress today, Dr. Benbrook. I have a significant number of additional questions that I will submit to you in writing, and also you, Mr. Guerrero. Because of a lack of time, we are simply not going to be able to go into it. I have about three pages of questions for you.

Senator Lieberman.

Senator LIEBERMAN. Thank you, Mr. Chairman.

Again, I thank both of you because you're both obviously independent and bring a fresh perspective, and also you show us what Senator Reid and I have talked about in length—you've showed us that Alar is the beginning of the problem, not the end of the problem, no matter what we do about it. I assure you that the chairman of this subcommittee and the members are going to hang in there and do what we can to see if we can change the underlying problem.

A few questions, if I may: this chart is intriguing because it shows us this list of the chemicals that are causing most of the health problem. Let me see if I can understand what you're saying about why EPA can't do what would seem logical, and that is to get at these.

Is the basic problem the risk-benefit analysis; that is, that they can't simply knock something off the market because it has adverse health consequences if there's no replacement for it and, therefore, there is a strong economic benefit to it?

Mr. BENBROOK. The FIFRA statute requires the EPA to come forward with an extremely refined and sophisticated analysis of both a pesticide's risks and the benefits. Until it has all the facts, it really is irresponsible for the agency to try to cancel or suspend a pesticide unless there is an imminent hazard.

This phrase was used by the earlier panel, and this is a provision in the law that says if a new study has come forward with extraordinary results indicating a level of risk completely unanticipated in

earlier studies, then the agency can act. Dr. Moore will express to you, I'm sure, later that they thought about an imminent hazard suspension of Alar, but they just didn't think that the data was compelling enough, nor is it responsible regulatory policy to take such an action based on an interim kill in a two-year study.

But there was at least some thought of that. The problem is there is no interim regulatory authority for EPA. It can't reduce risk 50 percent while it studies and gathers more information. It either has to go all the way with a complete data set, or not at all.

Mr. GUERRERO. Senator, if I may add a perspective on that——

Senator LIEBERMAN. Yes, please.

Mr. GUERRERO [continuing]. Because it's a very complex issue. When we talk about older pesticides, the existing pesticides that have been registered previously for use and for which EPA is now re-registering and re-examining these tolerances, there are a number of things that complicate it.

First, for many of those tolerances, they were established without adequate data on the chronic, long-term health effects, the concerns that we have been talking about this morning in particular.

Secondly, to develop those studies takes time. It can take up to four years to develop that data.

It's an iterative process. EPA goes back and forth and says, "Show us data." The industry shows it data. It looks at the data and says, "Show us more data." And it goes on.

Thirdly, as my colleague here on the panel indicated, FIFRA is a risk-benefit statute, so that once the data does indicate there are problems of concern and those products go into the "special review" box, there's a fairly lengthy process in terms of weighing the benefits with those risks. That's not easy.

Then, finally, when a decision is reached, there is an administrative process that is cumbersome. That takes time and a registrant can challenge that process in the courts, and that can take many years to play out.

When you combine all the uncertainty and you combine the procedural and administrative aspects of it, that accounts for a good amount of the effort.

Senator LIEBERMAN. So the answer is to alter the current risk-benefit requirement and have a system that is, as Mr. Nader said, health-based; that is, if you find a risk to health, that's it?

Mr. BENBROOK. Our committee recommended that the application of a consistent risk-based, negligible risk standard to new and old pesticides, to residues in fresh and processed foods could bring about approximately a 90 percent reduction in risk. Behind our committee's recommendation was the recognition that when risks get above a certain level, we really should not be concerned about benefits. Regulatory action should be taken. Our hands should be washed of the chemical. American agriculture will get on.

At some negligible risk level the consideration of benefits—for example, as EPA considers regulatory actions on these eight oncogenic fungicides, we can probably reduce risks from the fungicides by 90 percent but retain several of them for use in those seasons when a plant disease problem gets out of control.

In other words, we can reduce 80 or 90 percent of the risk, but retain a large measure of the benefits if we go about it in an intel-

ligent, sophisticated, and orderly way. We have not been doing that. We have no way to begin to squeeze the excess risk out of the food supply, and that is the authority that EPA needs, the legislative fix, if you will.

Senator LIEBERMAN. Okay. So that's one area which we should look at. Let me ask you a little bit about risk—if I may, Mr. Chairman, just briefly.

What does it mean when we say a risk is 1 in 1,000 in terms of a carcinogenic?

Mr. BENBROOK. It's an estimate of excess lifetime cancer risk above the general rate of cancer in the population. One of four of us, regrettably, is going to get cancer in our lifetime. Any chemical, whether it's an air pollutant, a water pollutant, in the food, a food additive, that increases that risk load by 1 in 1,000 is adding 0.001 to that 25 percent. Over a lifetime 1 in 1,000 additional Americans would get cancer from that risk.

Senator LIEBERMAN. Additional risk associated with that product?

Mr. BENBROOK. Yes, with that chemical. So, as Dr. Lajinski explained last night on the "60 Minutes" show, such chemicals add to the pool of chemicals in the environment that are causing this cancer load.

Senator, frankly, we do not have scientific knowledge to prove that chemical A, chemical B, lifestyle factor A or B causes so many cases of cancer. It's still quite a mystery with the exception of a few very clear carcinogens like vinyl chloride and tobacco.

Senator LIEBERMAN. This is the problem that lay people like me have in dealing with this. One of the studies that I read said that in 1985 EPA had concluded that the risk from daminozide, Alar, was—or perhaps it was the breakdown, UDMH—was 1 in 100 for infants, 1 in 1,000 for adults. Now that says to me that 1 out of every 100 infants over the course of a lifetime, because of the product eaten, might die earlier as a result of that product. To me, that sounds like an imminent hazard. Therefore, to me, it seems to be justification for more aggressive action by EPA than we've seen.

Mr. BENBROOK. If any Federal regulatory agency or official felt they had plausible data indicating a risk of 1 in 1,000 for any chemical, it would be gone tomorrow. I'm sure Dr. Moore will express that to you.

There are a set of assumptions, worst-case assumptions, that can lead to some very high estimates of risk and would translate into tens of thousands of cases in the human population. Fortunately, there is reason to believe that that isn't occurring.

But, the point is there is an awful lot that we do not know and we will not know for a generation or two. The question is, How prudent are Federal regulatory agencies going to be in experimenting with the health of the American population? That's the question.

Senator LIEBERMAN. My time is up, but I agree that, again, from a lay point of view and a citizen, parent, I'd rather have us be safe than sorry.

Senator REID. Dr. Benbrook, we have been given the benefit of your charts in preparing for this hearing. They are excellent. I am sorry that we didn't have time to go into them because the work

was certainly warranted, and it's been a big help to the committee and staff.

Senator Warner.

Senator WARNER. Just a question to Dr. Benbrook.

Let's go back to the question of the Congress taking upon itself the responsibility to examine the advisability of doing a surgical incision on one product. I don't intend to move on it until I've consulted with a very broad range of individuals because my style up here is to go carefully, but when I decide to move, I move.

Now you've got a marketplace which is in a shambles. I can show you articles about my State detailing stockpiles of apples rotting, people won't use the juice; we've got a problem out there.

This particular chemical is used in other agricultural products. It seems to me that that chemical is irretrievable. It has now been identified as likely to contribute to a whole series of physical problems.

To go out there and quickly move it away seems to me to initially serve a public purpose not only healthwise, but the whole infrastructure of people who are dependent on the marketing of apples and distribution who are getting injured because they had complied with the law.

You said—and I think you're probably right—that it could dampen some of the enthusiasm to move ahead here in the Congress, but I would question that. I think we're going to move ahead. I know we have to move ahead. With this fine and able chairman here, under his leadership we are going to move ahead.

But let's think through just doing this one to relieve the emotional stress and strain on a lot of people who are being innocently hurt and not set a precedent so that Congress is going to periodically dart out on these things. Hopefully, we'll revise the law, let the Executive branch once again take charge of these issues, and go about it in a methodical way.

I wonder, in light of that observation, if you would reconsider some of your views.

Mr. BENBROOK. Senator, the responsible way for the apple industry in this country to deal with the daminozide problem at the present time is for the manufacturer of the product, Uniroyal Chemical Company, and the major apple producing organizations to announce this afternoon that they are going to suspend sales of the product for the forthcoming crop season and subsequent seasons until the health issues that are raised by Alar are resolved to the satisfaction of the American public. That action can be taken this afternoon. Even speedy action by the Senate probably can't get a bill through today.

The way that—Senator, what I would urge you to proceed is to focus on the issue of negligible risk, which is what our report was about. Dr. Moore will testify to it. Legislation that would be very constructive would provide the EPA with realistic regulatory tools to reduce, for example, 30 percent of the negligible risk in the food supply for three years in a row. That could be done consistent with existing law without imposing horrendous costs on agriculture, and in a relatively short amount of time I think restore a very high degree of confidence in the American food supply.

Frankly, it is not warranted for there to be a consumer panic about pesticide residues in the food supply. There is no imminent hazard. What there is is a regulatory program that's not working with sufficient prudent concern about what those risks might be in the future.

We can't prove that the risks are there. On the other hand, there's enough suggestive data that the risk could be quite significant to children and risks of neurotoxic and immunological effects that we really haven't even begun to study.

I think that there is a responsible way to proceed. Your colleague, Senator Kennedy, has introduced a sweeping piece of legislation, as has Congressman Waxman on the House side. That goes to the heart of establishing a risk-based standard and a more rational tolerance-setting process. It implements the basic recommendations in our report by bringing about a consistent application of that standard.

Passage of that bill will resolve this problem for the entire list.

Mr. GUERRERO. Senator Warner, if I might observe on that point?

Senator WARNER. Yes, surely.

Mr. GUERRERO. Whatever the Congress is inclined to do regarding Alar and the need to reassure the public, one of the things I would like to observe is that it will be critical over the next few years as the EPA implements the FIFRA 1988 amendments that there be strong and continued effective congressional oversight.

When we did the chart for the Congress that we presented here in 1986, we had a heck of a time verifying the data that was supplied to us because EPA did not have a management information system in place to give accurate data on the status of that program.

When we came back three years later, to update that chart, we also had a heck of a time updating and verifying that information because EPA still does not have a management information system to give us a good snapshot picture.

We strongly urge this subcommittee to use that chart, to use it to hold EPA accountable for the progress in their program and to take appropriate action when necessary to keep that progress going.

Senator WARNER. I thank the Chair, and I thank the panel.

Senator REID. Senator Lieberman, you had an additional question?

Senator LIEBERMAN. I did, Mr. Chairman, just to make one point to Mr. Guerrero. I can appreciate all his testimony and work here.

I just would note that the chart that you've given us does indicate that, as of April 28th of this year, there were 1,300 active ingredients on pesticides that were undergoing the reregistration process, and not one of those product registrations had been completed. There's a lot that remains to be done. Process is moving very slowly.

I want to go back to one line of questioning with you, Dr. Benbrook, if I may.

In the course of the investigation I've come across some information about Captan which is the second fungicide listed on your chart and I gather, therefore, thought to be one that has serious consequences. I gather that the National Cancer Institute found in

1977 that Captan was a carcinogen. EPA initiated a special review in 1980. In 1989 Captan is still being used on the food we eat.

Now I understand that EPA recently determined that it is necessary to reduce our exposure to Captan and eliminate its use on certain foods and vegetables, but this is where my question is, and I am going to ask Dr. Moore as well. It has eliminated Captan from being used on what I would consider to be minor fruits and vegetables like leeks and quince, whereas it continues to be used, I gather, on strawberries, cherries, and grapes. I don't know about your family, but my family eats a lot more strawberries, cherries, and grapes than they do leeks and quince.

Mr. BENBROOK. Are quince a big crop in New Jersey, Senator.

Senator LIEBERMAN. It beats me.

Mr. BENBROOK. I don't even know what they are.

Senator LIEBERMAN. Let me ask you if you're familiar with that process and how you evaluate it and why it's occurred.

Mr. BENBROOK. Well, Senator, we've followed the Captan decision very closely because when it was announced, the EPA acknowledged that the Captan decision was the first application of the recommendations in our report which in October of 1988 the EPA said in the Federal Register it was going to adopt in its subsequent regulatory actions.

The concern that I and several others have with the Captan decision is very simple. The EPA came down very hard on 42 uses of Captan on some minor crops, and some major crops on which very little is used. It cancelled those tolerances. So it squeezed out of the food supply a lot of sanctioned risks, risks that would be legal, perfectly legal. But by focusing on those uses where not much Captan is used and really leaving untouched most of the major uses of the chemical, obviously the decision has had modest impact on actual risk.

Now in the decision document EPA said that it had received actual residue data that suggests that the risk of Captan on these major crop uses was far below the level of risk suggested by the published tolerance, which is a fact that everyone knew 15 years ago. But for reasons that I hope you'll ask Dr. Moore later, they did not at the time of announcing the Captan decision lower any of those tolerances for which it had information used in its risk assessment that actual residue levels are an order of magnitude (a factor of 10) lower, perhaps even lower.

Our report would have directed the agency at the time of making a judgment that those uses of Captan did not pose more than a negligible risk, that the tolerances should be lowered down to that level.

The problem with the Captan decision and the problem with EPA's implementation plan is it leaves until tomorrow, maybe sometime next century, dealing with tolerance adjustments in the context of a final re-registration package.

I don't think that that's going to regain the confidence of the American public in the food supply. It is true that Captan risk from registered uses rarely are at that level, but they could be, and the EPA would be powerless to do anything about it. The FDA would be powerless to do anything about it.

Senator LIEBERMAN. Very briefly, Captan is a so-called older fungicide. I presume that nobody would argue that, with the current state of data about it, that it would be registered today as a new pesticide?

Mr. BENBROOK. No, it would not be, certainly not for the vast majority of uses, because the EPA defines a cancer risk of 1 in a million as negligible.

Senator LIEBERMAN. For a new pesticide.

Mr. BENBROOK. For a new pesticide. The total risk of Captan is five times ten to the minus four. That's 250 times higher than 1 in a million.

Senator LIEBERMAN. Right.

Mr. BENBROOK. So there probably could be some uses of Captan that would not trigger the negligible risk standard, but it's a chemical that has to be used very cautiously because it is quite potent biologically.

Senator LIEBERMAN. So you'd say that the EPA decision on Captan does not adequately protect the public?

Mr. BENBROOK. I think it raises serious questions about the even-handedness of applying a negligible risk standard. Our report came about because of an inconsistent standard between fresh foods and raw foods. In our analysis we discovered that 90 percent of the risk came from old pesticides.

Well, if EPA comes forward with a stricter standard, but only applies it to new pesticides, that's only going to aggravate the inconsistency between the treatment of new and old pesticides, and that is not the way we're going to solve this problem.

Senator LIEBERMAN. Thank you.

Senator REID. As I indicated earlier, we may have additional questions we'll submit to the witnesses.

Thank you very much for your testimony.

The next panel of witnesses will be Dr. Steven Markowitz, Mt. Sinai School of Medicine, and Dr. Ronald W. Wood from the New York University Medical Center.

Gentlemen, while you're coming forward, I would ask that you stand and raise your right hands and be sworn, please.

[Whereupon, the witnesses were sworn.]

Senator REID. Gentlemen, before you begin your testimony, I would like to mention that Senator Lieberman and I have had some experience dealing with areas that I think you're going to testify about. We had a hearing on March 6th regarding composite materials, the materials that are used to make certain types of aircraft and other things. Here's what one woman testified to. I'm just telling you this just so that you'll get kind of a feeling of what we're used to.

I'm not the same person I was five years ago. I used to be very energetic. I always had something going on. There was never a time when I didn't have some kind of a project going on, doing something. But that's not the case anymore. I can't pump my own gas. I can't go out in traffic. I have vision problems. I can't go to the grocery store without getting sick. My kids, who are in their early twenties, don't understand what's happening to me. I can't sleep at night. I can't eat. I have no energy. I mean, there are days when it's all I can do to crawl from the bed to the couch so that I don't have to lay in bed all day.

You do dumb things. You take all the precautions in the world, but it still happens. One example, I was going to the doctor. This was last summer and my car had

been parked outside. I had a sun shade in the windshield. I don't know how I did it, but I forgot to take the sun shade out of the windshield and left to go to the doctor. Everybody was honking their horns and pointing and hollering at me, but I did not know—I did not know why they were doing this. I couldn't, I just couldn't make the connection to understand what they were talking about.

Finally I stopped and got out, went around the car to try to determine what was wrong. A guy stopped and said, "Hey, lady, you can't be driving around with that sun shade in the window." That's when it hit me. You just can't make these connections.

There are days when I don't even know if I'm in my own home.

Dr. Markowitz, would you proceed? You have five minutes to summarize your testimony.

STATEMENT OF DR. STEVEN B. MARKOWITZ, DEPUTY DIRECTOR, DIVISION OF ENVIRONMENTAL AND OCCUPATIONAL MEDICINE, AND ASSISTANT PROFESSOR OF COMMUNITY MEDICINE, MT. SINAI SCHOOL OF MEDICINE, NEW YORK, NY

Dr. MARKOWITZ. Thank you for inviting me here today.

My name is Steven Markowitz. I'm deputy director of the division of environmental and occupational medicine at Mt. Sinai Medical School in New York City. I am a physician specializing in occupational and environmental medicine, and a significant part of my research and clinical activities at Mt. Sinai involve the assessment of the human health effects of pesticides.

I'd just like to make a few comments and focus my remarks on the neurotoxicity of pesticides. First, it's important to recognize that we're largely ignorant of the human health effects produced by exposure to the 600 or more active pesticides currently in use. A review of this topic by the National Research Council in 1984 concluded that a complete health hazard assessment on pesticides was currently only available for 10 percent of all pesticides, and that for two- thirds of pesticides we had either no or minimal toxicity information regarding their effects on humans or animals.

The Environmental Protection Agency has similarly found a massive absence of data in its attempt to evaluate the safety of pesticides over the past decades. Therefore, whatever we claim currently to know about the potential human health problems associated with pesticides is clearly dwarfed by our ignorance about substances to which we have daily exposure.

One of the few areas of pesticide toxicology in which we do have limited knowledge is on the impact of selected pesticides on the human nervous system. While much attention has been appropriately focused on the carcinogenic effects of pesticides, it would be unwise to the slight the human nervous system as an important target organ for the action of pesticides absorbed into the human body.

There are two classes of pesticides currently very commonly in use called organophosphates and carbamates, of which the principal site of toxicity is the nervous system. They have been proven in humans to produce two distinct neurologic syndromes. Organophosphates and carbamates are acutely toxic to the nervous system. This means that with sufficient exposure suffered in a short period of time, they will produce irritability, anxiety, muscle twitching, widespread autonomic nervous system disfunction, seizures, coma, and even death.

All members of the classes of organophosphates and carbamate pesticides are toxicologically similar in that they have a common mode of action in disrupting the nervous system. These pesticides have served as the principal replacements for DDT and its relatives over the past 20 years.

Paradoxically, due to their acute high toxicity, the newer chemicals, the organophosphates and carbamates, have probably caused more immediate deaths than have the older chemicals such as DDT.

A second neurologic syndrome related to organophosphate pesticides is that of delayed peripheral neuropathy. Several members of this pesticide class can produce not only the immediate neurologic symptoms that I mentioned above, but also crippling long-term damage to the nerves and arms of affected individuals. This disease occurs in humans beginning several weeks after last exposure. Most of these neurologic effects have occurred after clear-cut circumstances of exposure.

Aside from these two distinctive neurologic syndromes, there is a growing body of evidence that low-level chronic exposure to pesticides can produce neurologic symptoms. To date, these studies have been completed in occupational groups and showing that a daily exposure to pesticides, not in sufficient quantities to produce acute poisoning, but at much lower levels, can produce neuropsychological deficits, including problems with memory, concentration, perception, and other mental processes. This is an area of increasing concern and research given the widespread, low-level exposure to pesticides.

Let me just move ahead for a moment to the NRDC study. They used specific food consumption patterns and applied what is known to be the exposures from residues on foods, both coming from the 1980s, and estimate that three to ten million children on a daily basis receive excessive exposure to organophosphates, which are the chemicals that I've just mentioned which are known to produce neurologic disease in humans.

The actual studies that we have of children in terms of showing neurological or neuropsychological deficits are nonexistent, to my knowledge. We, therefore, have to rely on animal data and, to some extent, on occupational studies and infer from there in terms of protecting children's health.

I think that the example of another well-known neurotoxicant for children can be illustrative. In the 1960s when childhood lead poisoning became an issue of broad public concern, the principal health focus was on preventing clinically overt lead poisoning, which is basically encephalopathy or brain swelling produced by high levels of lead.

The acceptable limit of lead in the blood was at that point considered 50 micrograms percent. In the intervening two decades, as more sophisticated studies have been completed, the level of blood lead considered acceptable has been lowered several times and is now presently 25 micrograms percent, one-half of what it was 20 years ago.

This change has occurred in response to an increasing appreciation that low levels of lead are associated with a wide range of neuropsychological deficits. Recent alarming studies have shown

that blood lead levels in the range of 10 to 15 micrograms percent during the prenatal period are associated with developmental problems in children for at least several years after birth.

Prior to the reduction of the use of lead in gasoline, the average adult blood lead in this country was 15 micrograms percent, meaning that 10 years ago, prior to the reduction in the use of lead, the average urban pregnant woman would have had a level of blood lead which is now known to be toxic.

This shows that for a widespread neurotoxin such as lead, as we've increased in our understanding of its ability to affect the brain, we've decreased the levels that have been considered acceptable.

Now what can we do with this knowledge? Part of the problem with pesticides is that we don't have an easily measurable means of assessing exposure. We don't have a blood level of these pesticides that we can measure, making these studies much more difficult.

However, the known human neurotoxicity of pesticides, the age-related susceptibility associated with pesticide exposure, and the exposure estimates obtained from EPA and FDA data applied by the NRDC point to a need for significant reduction in the use of pesticides for reasons of neurotoxicity, not to mention carcinogenicity.

I think there are three steps we can take. One is thorough testing prior to using these chemicals, requiring of the companies that a whole range of tests be done including tests for chronic low-level exposure relating to neurotoxicity, that is, neurologic outcomes.

Second, pesticides on foods should be monitored more closely. In the FDA program only 50 percent of pesticides are detected, can even be detected by the tests currently used.

Finally, we should reduce the tolerance levels, because it should not be assumed that children are exposed to a single pesticide at a time, but are exposed to a whole class of, for instance, the organophosphates which work together to produce neuropsychological deficits.

Senator REID. Dr. Wood.

STATEMENT OF DR. RONALD W. WOOD, RESEARCH ASSOCIATE PROFESSOR OF ENVIRONMENTAL MEDICINE, NEW YORK UNIVERSITY MEDICAL CENTER, REPRESENTING THE AMERICAN PSYCHOLOGICAL ASSOCIATION, WASHINGTON, DC

Dr. WOOD. Mr. Chairman, it's a pleasure to be here today.

I think Rachel Carson would share your concern about the neurotoxicity of pesticides. In 1962 in her famous book, "Silent Spring," which was responsible for implementing expanded regulation of pesticides in this country, she stated, "Confusion, delusions, loss of memory, mania—a heavy price to pay for the temporary destruction of a few insects, but a price that will continue to be exacted as long as we insist upon using chemicals that strike directly at the nervous system."

I think Dr. Carson would be amazed 27 years later at the state of pesticide regulation applied to the prevention of neurotoxicity by the EPA and FDA.

Today I appear before you representing the American Psychological Association, a group of 90,000 psychologists interested in normal and abnormal psychological functioning. I'm chairman of a committee that was formed 10 years ago to examine how EPA conducts neurobehavioral toxicity testing. This effort is focused mostly on TSCA, and our interests have moved more recently to testing under FIFRA.

We share concerns about many of the acts within the jurisdiction of this committee, and Dr. Balster of the Medical College of Virginia, a member of my committee, testified recently on the toxicity of materials used in the aerospace industry. The issues which he raised in his testimony apply here as well. There's woefully meager data on these chemicals, and workers are at a distinctly elevated risk of injury.

We share with the Natural Resources Defense Council their concern about insecticide residues, but we arrive there by a different route. We are concerned about chemicals present in food and drinking water and their chronic effects, especially in children.

However, we also believe that there are levels below which there is no risk for most chemicals. NRDC asserts the daily intake exceeds the allowable daily intake, the prescribed amount that should be safe. Our concern arises from the adequacy of the data on which the ADI is based.

The current situation is that, with the exception of the organophosphate-induced acetylchlolinesterase inhibition, which the previous witness spoke about, the agency relies on an assumption that protecting against other effects will protect against neurotoxicity. We think this is a dubious assumption at best for agents that are designed to affect the central nervous system.

Under current testing, there is a very limited amount of central nervous system evaluation. There's a test in the hen, which is a non-mammalian test for one specific kind of injury; there are some primitive cage-side observations of the well-being of animals, and there is a cursory, and, in our opinion, inadequate examination of the brain.

In the Office of Toxic Substances, the sister office of the Office of Pesticides, they have promulgated guidelines which, although not on the cutting edge of modern neuroscience and psychology and not widely required in the regulatory programs of that office, they are much better. We entered into a petition to the agency to encourage the Office of Pesticides to adopt those guidelines for the routine evaluation of neurotoxicity.

We could turn now to the summary of my recommendations on page 1 of the testimony. We are encouraging the agency to test pesticides and their inert ingredients for neurobehavioral toxicity on a routine basis. EPA certainly needs more staff with expertise in neurobehavioral toxicity evaluation in order to deal with this increased data flow and to establish new testing requirements.

Now since this is a relatively new activity for EPA, clearly there is a need for improved surveillance of worker populations involved in manufacturing, mixing, and applying these chemicals. We think that workers are at a much higher risk than the general population because of their increased exposure and I believe, along with Mr. Reid, that workers deserve a safe workplace.

The implications of the improved testing for neurotoxicity extend beyond our national borders. They go into third world countries as well. This has been recognized by the Pan American Health Organization and the World Health Organization, and I think there is much to be learned by studying workers in our country and abroad.

Any testing procedure that we set up to routinely look at a large number of chemicals is going to miss a large number of bad actors. We need an effort to see what forms of toxicity we're going to miss with these relatively low-level tests that would be looking at the toxicity of chemicals present in our food supply and drinking water.

This should be done by incorporating testing into the research programs of the National Toxicology Program and EPA. We encourage the regulated industry to develop its own organization for conducting basic research into the toxicity of pesticide formulations.

We call for a massively expanded research program in this area. I think that this is an area where the National Academy has pointed out an extensive testing need for greater information about neurotoxicity of chemicals throughout our society. Without the implementation of such a program, we're just not going to have the information necessary to increase confidence in the regulatory programs of this country that we can have safe workplaces and safe market baskets.

Thank you.

Senator REID. Dr. Markowitz, if children are exposed to levels of neurotoxic pesticides above the allowable daily intake, tell us in laymen's terms what effect this can have on a young person?

Dr. MARKOWITZ. First of all, I should point out that those studies have not been done in children, so this is based on other types of neurotoxicants as well as some animal studies. There would be learning problems. There might be some problems with attention, concentration, ability to absorb material, basically problems with cognition.

Senator REID. You heard the statement that I read, that testimony came from a woman who complained of problems arising out of her work with composite materials. Even though she is an adult, is that a description of—we're here talking to the two panelists, Dr. Markowitz and Dr. Wood—the kinds of problems that people get?

Dr. MARKOWITZ. In the spectrum, yes. In other words, there would be variable response. What you described was an extreme example. That will occur among a minority of the population exposed to neurotoxicants at a certain level.

Of greater concern in some ways is a much larger group that would be exposed and suffer lower-level symptoms than that, not as dramatic as that, but, nonetheless, in a daily way would impair in two-year-olds or five-year-olds or ten-year-olds their ability basically to learn and their ability to develop in a healthy fashion emotionally and mentally.

Senator REID. Dr. Wood, would you agree?

Dr. WOOD. Yes, I think that there is a likelihood that there may be cognitive effects or intellectual disorders produced by exposure to many of these chemicals that are used as pesticides, but in all

fairness I think that our knowledge is very inadequate about the effects at the levels which are present in our current food supply. We need a great deal more information before we can get a handle on the extent of this risk.

Senator REID. If your information is minimal at this point, does that mean that the information that you two gentlemen have is not of sufficient weight to deem it necessary to go into the neurotoxic effects of pesticides, or is this just an academic experience of yours that you want to go into?

Dr. WOOD. Oh, I'm very concerned or I would not be here today.

Senator REID. What do you base that on?

Dr. WOOD. Well, on the observations of high-level experiments in humans and in laboratory animals.

Senator REID. But I thought you said we hadn't done any.

Dr. WOOD. We haven't done any very low-level experiments on developing organisms, certainly not in children. Perhaps some of the widest data that's been collected in humans is on the effects of organophosphates that has been conducted by the army in the development of chemical warfare agents.

The National Academy of Sciences published a document on the possible long-term health effects of short-term exposure to such agents; in the first volume of this three-volume series, they expressed their concern about this. They saw in some individuals electrical changes in the brain which persisted up to a year after these high-level exposures to these materials.

So I think there's plenty to worry about, but I'm worried about trying to make a judgment for the Nation's food supply where risks are not very well characterized and try to balance that health risk against the benefits of having fresh fruits and vegetables present in the supermarket.

Senator REID. Dr. Markowitz.

Dr. MARKOWITZ. I agree that the information base for neurologic disease is much less developed than, say, for cancer. There has been a war on cancer but no war on neurologic disease in this country. The neuroscientific work that's got to be done both from a biological base as well as in human clinical disease has really just been developing over the past decade or so.

However, if we accept the concept of an ADI, of acceptable daily intake, recognizing that at levels just above that intake, you probably will not see effects because there's a safety margin, there's a safety factor built into the concept of the ADI.

Then if you examine specific consumption data and find that the kids are routinely exceeding the ADI for neurotoxic agents, the organophosphates, then it's not clear that there will be a health effect at that level, but it's clear that there should be concern.

Given the difficulty of studies in this area, the question is at what point do we intervene, at what point do we make changes to protect people from getting sick?

Senator REID. Senator Lieberman.

Senator LIEBERMAN. I gather we're on the frontier here, but both of you agree that it's a frontier we ought to be concerned about.

Who decides what the allowable daily intake of one of these potentially neurotoxic chemicals is?

Dr. MARKOWITZ. I think the ADI is set by the EPA or perhaps some input from USDA or FDA.

Dr. WOOD. EPA makes, formulates that recommendation.

Senator LIEBERMAN. Okay. What it means in simple terms is that, if we take in more than that amount, there is a danger of neurotoxic effect on our system; is that correct?

Dr. WOOD. They recommend that as something which is permissible, and it's not clear what the extent of risk is by going above that. That value is set by setting a number of safety factors on an experiment in which they detect no effect. Now those experiments that detect no effect may fail to detect an effect because they're lousy experiments, but they also may be too conservative, if you will.

I think we should face the possibility of actually putting EPA in a position of potentially recommending a higher permissible level of neurotoxic materials in our foods if our information is improved so that we say that the risk is, in fact, less than we had originally estimated.

Senator LIEBERMAN. So then both of you feel there is something here to worry about? I presume, Dr. Markowitz—you said that if you were slightly above the ADI, there would be something to be concerned about, but perhaps you couldn't conclude that there would be a direct health—presumably, if you're way above it, then there's more reason to be concerned?

Dr. MARKOWITZ. The way the ADI is set is to do a series of experiments at different levels of exposure, find a level of exposure at which there is no effect, then not proclaim that a safe level but put in a safety factor, usually one-hundredth of that, and then set the ADI.

There's a built-in safety factor.

Senator LIEBERMAN. Okay. There's some basis to all that. Now what about the NRDC numbers which suggest that 17 percent of children are being exposed to neurotoxins?

Dr. MARKOWITZ. That translates into millions of children, so it should be of alarm not just to you, but to many others.

What the NRDC did is to address an issue which came up earlier today, which is to look at multiple exposures, look at not just exposure to a single organophosphate pesticide and whether a child is consuming too much of just that one pesticide through a variety of food products, but NRDC translated exposure to a number of organophosphates—I believe the number was 10 or 14—and combined them into a common unit and then looked at the total of organophosphate exposure, coming up with numbers of children with total pesticide consumption above the ADI.

That is not an approach that EPA has taken, to my knowledge. It should be taken.

Senator LIEBERMAN. Let's talk a little bit briefly about what EPA is doing. I gather that EPA does test pesticides for some acute neurotoxic effects; is that correct?

Dr. MARKOWITZ. That's correct.

Senator LIEBERMAN. When we're saying "acute," they're aiming to determine whether a chemical may cause truly acute effects such as paralysis or death?

Dr. MARKOWITZ. That's correct.

Senator LIEBERMAN. Do they require that pesticides be tested now for chronic neurotoxic effects that might be caused by lower levels of exposure?

Dr. WOOD. Essentially the extent of their testing for chronic neurotoxicity is either a test in hens which evaluates one specific kind of neurotoxicity or they do a very crude look at the animal by walking up next to the cage and saying, "Well, it looks okay to me." But you would miss a very large number of chemicals using techniques of that nature, and they do not, in fact, use any of the techniques that the drug industry uses to examine new drugs before they would be offered for human consumption.

Our concern about the allowable daily intake is that it is not based on any reasonable data focussed specifically on neurotoxicity. They assume that by protecting against other kinds of injuries that they will observe in those animals, and by putting a large safety factor on it, that they are protecting against effects on the nervous system. Many insecticides are designed to have selective effects on the nervous system, so I would challenge that assumption. That is clear.

I would like to say that I also have a 16-month-old baby and I have confronted this issue in my household. We wash our vegetables and we eat a wide variety of vegetables. This is the recommendation of the National Academy of Sciences in their book, "Toxicants Occurring Naturally in Food", in order to cut risk and distribute it across our different food supplies.

It's definitely a balancing act here against having inexpensive, nutritious food which we know—fruits and vegetables—have nutritional benefits, and we want to make those foods available to a very wide part of the American populace. There may be selective deprivation of fresh foods and vegetables to those who cannot afford organic produce, and this is another factor in the balancing of risks and benefits that's solely based on health.

Senator LIEBERMAN. Very briefly, because my time has expired, what's the one thing that, if we were designing the system now with some sensitivity toward neurotoxic effects, that we should change, that we should do differently than we're doing now, the "we" here being Congress creating the Government oversight system?

Dr. MARKOWITZ. I'd have to say that we should move much more vigorously on premarket testing of chemicals so that before the public has exposure, we can be assured that they are safe in terms of neurotoxicity.

Senator LIEBERMAN. And you test for low-level exposure as well?

Dr. MARKOWITZ. Chronic low-level exposure, correct, in addition to what's currently done which is acute and subacute.

Senator LIEBERMAN. Thanks.

Senator REID. This subcommittee is going to stand in recess until 1:45 this afternoon. I apologize to panel 5 and panel 6—John Moore, John McCarthy, and Janet Hathaway—but the President's on the Hill and we have to meet with him.

We stand in recess until 1:45.

[Whereupon, at 11:59 a.m., the subcommittee recessed, to reconvene at 1:45 p.m. the same day.]

AFTERNOON SESSION

Senator REID. The subcommittee will come to order.

Our next witness will be John Moore, the Acting Deputy Administrator of the Environmental Protection Agency.

Mr. Moore, we appreciate your patience.

Would you raise your hand?

[Whereupon, the witness was sworn.]

Senator REID. We have your full statement and that will be made part of the record. I would appreciate if you could summarize.

STATEMENT OF JOHN MOORE, ACTING DEPUTY ADMINISTRATOR, ENVIRONMENTAL PROTECTION AGENCY

Mr. MOORE. Thank you, Mr. Chairman. I will just excerpt my testimony which is rather lengthy.

Let me say that in the years that I've been at EPA——

Senator REID. How long is that?

Mr. MOORE. I have worked at EPA since the fall of 1983, Senator. The focus of the pesticide program, from my perspective, has been and continues to be on the old pesticides and being able to get the old pesticide process up to the standards that we impose upon new pesticides; in other words, the standards of the eighties rather than the standards that might have existed at the time that they were registered some two and three decades ago.

The re-registration program I think has made substantial progress. It's still got an awful long way to go.

What we attempted to do early on was to identify key data elements that take a long time to develop just by the very nature of the test and to get those requirements imposed upon registrants so that we can get on with the work. We've done that in large part through a data call-in for all full-use pesticides and then in a more formal sense imposed registration standards at the rate of 25 per year. There's now just under 200 of those standards that are in place, which represent just under 90 percent of the total volume of pesticides manufactured in this country on an annual basis.

Twenty-four of those chemicals, I think in large part as a result of the process, are no longer on the market. In addition, since re-registration is basically imposing the standard of the eighties on old pesticides, there are another 50 active ingredients that are no longer on the market.

As you know, Congress passed what we refer to as the FIFRA 1988 amendments in the fall of last year which require EPA to accelerate the process of re-registration and, just as importantly, give us the resources to meet the deadlines that are imposed in that statute. We have met those deadlines contained in FIFRA 1988 and have every reason to believe that we will continue to meet the deadlines that are in the statute for the near- to the mid-term.

Let me focus on an issue that is particularly vexing, I think, to this committee and is problematic to the agency as well. That's the issue of reassessing tolerances as a consequence of pesticide use. As part of the re-registration process, although not mentioned silent in the FIFRA statute, we think one of the final chapters in the book called "re-registration" has to be visiting the food tolerances associ-

ated with those pesticide uses and either imposing them, lowering them, or eliminating them, as the data would deem appropriate.

In setting new tolerances or reviewing existing tolerances, the agency is concerned with protecting sensitive subpopulations. EPA's analysis of pesticides in the diet takes into account that children and infants typically eat more food in relation to their body weight and more of certain types of foods than does the average adult.

This approach is the result of improvements in the process which we have recommended over the past several years. I think we'll continue to apply this approach systematically in the re-evaluation of these old pesticides during the implementation of the FIFRA 1988 amendments.

As the agency obtains and reviews information on old pesticides, we will identify some which may pose previously unrecognized risks to people or the environment. We will then need to use our special review process, which may result in cancellation or suspension, to restrict or prohibit the use of some or all of these chemicals.

Limiting use of these chemicals by getting them out of the marketplace is, however, a slow, resource-intensive process. This process, called a "special review" process by the agency, does provide opportunities for public comment, from users, manufacturers, or any other interested parties as well.

FIFRA also requires that the agency send its proposed notices of intent to cancel to a group of independent scientific experts to get their opinion as well. After evaluating all of these comments, we make a final determination.

Under the current statute, this notice may be challenged in a trial-like administrative proceeding before an administrative law judge whose decisions may then be appealed to the EPA Administrator.

In my opinion, having a process of notice and comment preceding a final decision and then allowing a process whereby you can have an administrative hearing which, can in turn be appended to the Federal courts—pardon the pun—allows three bites at the apple.

Senator REID. You shouldn't have brought that up.

Mr. MOORE. I think that this is not in the public's interest. There's no need for that intermediate step if, indeed, we can allow due process in the front end of the process, and of course allow one access to the courts in a more traditional sense. It's without parallel in any other statute in the agency.

Mr. Chairman, my testimony goes on and gives some specific information on Alar as well as on Captan. In the sake of interest of time, I will skip those and just respond to any questions you may have in that area.

Senator REID. Thank you very much.

Mr. MOORE. Let me conclude by saying that I think our general risk assessment methodology is sound and our tolerance-setting system is protective of public health. However, the system is far from perfect.

We have taken steps to improve the process. A tolerance assessment system whereby we can calculate susceptible subpopulations is an example of an attempt to improve.

The Delaney paradox report that you heard summarized by Mr. Benbrook this morning is another example of a product that the agency sought while trying to work through the maize of old pesticides. The current study dealing with giving the agency advice as to whether or not infants are at special risk and, if so, what policy changes should one make in our operations. Those represent, I think, an attempt by the agency to try to get the best advice in making appropriate changes as is needed.

Let me just conclude that, while I think constructive debate on the pesticide issues is important, such a debate can only lead to a better system for all of us. These issues should not be divisive. We all want to protect public health.

However, I think some of the rhetoric that's been associated with pesticide residues over the last couple of months has skewed, I think, the public perception. If misinformation and fear dominate such debates, there's a very real possibility that we'll make poor decisions. I think if that happens, it's the public, including our children, who will bear the consequences of those failures.

Thank you, Mr. Chairman.

Senator REID. Thank you very much, Mr. Moore.

It's difficult to determine where we should start, but why couldn't we start by having an emergency order to suspend the use of Alar? It seems to me that you're going to get that anyway through some emergency legislation, and it seems the way things now stand everybody is losing. The apple growers are saying we've suffered tremendously. The American public, right or wrong, are afraid to eat apples and drink apple juice, especially when it involves children. The Congress is running pell mell toward doing something about Alar.

The testimony is replete this morning that Alar is only a sign of the times. It's not a cure-all. Certainly we realize that up here.

But why shouldn't we just stop Uniroyal from selling Alar?

Mr. MOORE. Well, Mr. Chairman, we announced in January, when we first discussed the extension of the tolerances on Alar, that we were going to move forward and seek cancellation of the product based on our analysis of interim data.

Senator REID. But, Mr. Moore, isn't there some emergency provision that you can go through to stop the production—I mean the sale of that?

Mr. MOORE. Mr. Chairman, there is a provision in FIFRA which allows one to suspend the use of a product pending the outcome of the cancellation hearings.

Senator REID. Why don't you do that here?

Mr. MOORE. In my honest opinion, at the time that we made the decision to move forward with cancellation and not suspension with cancellation. In my opinion, as we sit here today, the risks that are associated with Alar's use during the period of cancellation does not fit the statutory requirements that we think need to be met in order to invoke suspension.

Senator REID. Even in spite of the fact that the apple growers are suffering and in spite of the fact that the American public basically is afraid to eat apples? Shouldn't that be taken into consideration rather than the direct scientific formula that you and your scientists think should be followed?

Mr. MOORE. Well, I think such action, while I'm certainly perceptive of the public policy ramifications of taking such an action, would not comport with what the statute suggests needs to be done, and I am very concerned that it sets a dangerous precedent for the next chemical the next year or the year after coming down the road; that once you've made an exception for chemical A, you end up being hard pressed to re-establish that line for chemicals B, C, and D.

Senator REID. But doesn't that basically just shift the burden to the manufacturer once it's cancelled?

Mr. MOORE. In what way, Mr. Chairman?

Senator REID. Well, then they have to come forward to show that it's safe.

Mr. MOORE. Yes, if I was to make a suspension finding and I was contested in court, which is where one would go on a suspension action, I would have to defend that action in court and then obviously would still have to work my process through the cancellation proceedings and sustain the unreasonable risk as well.

I think if you want to have a different trigger, if you will, available to the agency for chemicals that maybe don't meet the rather demanding tests, in our opinion, under the current suspension activities, there should be a change in the statute that allows us to have a hair trigger, more of a hair trigger than we have right now.

Senator REID. Mr. Moore, I appreciate that. Now if, in fact, you did suspend or cancel the registration, or whatever the proper technical term is, Uniroyal couldn't go after the EPA and/or the Federal Government for damages under this statute.

Mr. MOORE. Correct.

Senator REID. The most they could do in this is say, "Hey, the product's okay; let us start selling it again." Right?

Mr. MOORE. Right. FIFRA 1988 eliminated any Government responsibility for costs of chemicals through suspension.

Senator REID. Mr. Moore, I think that you should return to the EPA and tell Mr. Reilly that there are at least two Senators—the first thing that moves on that Senate floor is going to be legislation to stop Alar. It would seem to me it would be to everyone's best interest for the agency to do it. I think our letter to Reilly indicates that is the case.

Now you say that we should do something to change the law, to make it—you're not saying we should do it, but, in fact, we feel that way, the law should be changed to make it easier for the EPA to do that. I'm giving you a charge to go back to the agency and meet with all your lawyers or whoever it's appropriate to do so, and then you come back to this subcommittee and tell us what changes you feel should be made in the law, because you understand we're dealing with composite materials, clean air, clean water, solid wastes, all kinds of things in this committee. Maybe we should know more than what we do.

The fact of the matter is we need some guidance from the Executive branch of Government to make it easier for everyone. We want to work with you. This committee wants to work with you, but right now this situation is most difficult. So will you do that—return to me with ways—alternative 1, 2, and 3 as to how the law could be changed? Okay?

Mr. MOORE. Yes, sir.

Senator REID. One last question: I know I've exceeded my time, but I'll take the chairman's prerogative and ask one brief question.

You saw the chart that was on the wall with Dr. Benbrook, and he had a long list of pesticides. Basically, the top ten—nine of them are fungicides. He said if you could get rid of those ten, then you'd be rid of 90 percent of the problem.

Explain to this subcommittee the difficulty in the law relative to old chemicals compared to new, because most all of those were old. In fact, nine out of the ten were old.

Mr. MOORE. All right. I was not here, but I think I've seen Chuck's charts in other circumstances in the past.

In essence, I believe his chart is reflecting a table out of the Academy report of a couple of years ago in which, as you say, most of them are fungicides.

I think what he was pointing out——

Senator REID. And they're all old.

Mr. MOORE. Yes. I think what he was pointing out is that the committee's opinion was that the theoretical calculations of risk of those are such that if you could treat with the ramifications of those ten materials, you would be addressing 90 percent of the calculable risk that's associated with those materials.

We have focused on those tables in the Academy report as far as giving them high priority attention. The main thing that we were lacking at the time this document was put out was exposure data. Most of the Academy's recommendations were made on theoretical calculations which assume that 100 percent of the crop treated and 100 percent of the legal residue was on every food commodity for which it was licensed. This is a very, very conservative calculation which usually bears absolutely no resemblance to actuality.

What we have had to get in order to get a better sense of exactly what are the more realistic risks would be the residues of these chemicals on the crops for which they are registered. We have been doing that in a systematic fashion.

For example, we finished Captan, which is the second one on that list, in February and announced what changes we would be making. For a number of the other chemicals on there, they all fit a category, if you will, called EBDC fungicides. We expect by the end of this month to announce our proposed course of action on that group of chemicals collectively.

But in the main, for the chemicals of this sort, it usually is a lack of reliable exposure data to come up with meaningful estimates of risk.

Senator REID. How do you get better exposure data?

Mr. MOORE. Basically, put a requirement on the producer or producers of the material to generate such data.

Senator REID. But that could come administratively. That need not be legislation; isn't that correct?

Mr. MOORE. No, we have adequate authority currently to require such information. What is frustrating, I think, in many circumstances, or at least is frustrating to me, is that when you have some evidence that suggests a chemical may have some adverse toxic consequence, whether it be cancer or some other type of toxic effect, and you know you don't have meaningful exposure data,

that in order to generate meaningful exposure data you often have to wait a year or two years for that data to be generated because of the fact that you usually have to develop it through the normal cycle of agriculture in this country.

Senator REID. Yes, but, Mr. Moore, some of these products go back to 1955.

Mr. MOORE. Correct.

Senator REID. Senator Lieberman?

Senator LIEBERMAN. Thank you, Mr. Chairman.

Dr. Moore, thank you for being here. May I say to you that I don't enjoy being cast in an adversarial relationship with EPA. I think all of us on this committee would like to be supportive. Part of our role is EPA oversight. I'm also mindful that you've testified this morning and you've indicated before, both in testimony before Congress and publicly, that part of the problem is the laws, the authority that you have.

I do believe that part of the problem, unfortunately, has also been the way in which EPA has carried out some of those laws. Let me just ask a few questions about them.

First, I want to pick up on the chairman's charge to you to go back to EPA and raising the questions also, particularly, of reconsidering whether it is not possible to suspend Alar now. I understand what you're saying about the need to find an imminent hazard, but, as I'm sure you know, the word "imminent" is used in so many other environmental statutes—a few citations: section 106 of the Superfund, section 7003 of RCRA, section 504 of the Safe Drinking Water Act. It's in the Clean Air and Water Act.

Under each of those statutes, to the best of my knowledge, EPA has at various times urged courts to adopt a very broad interpretation of the word "imminent," which is to say that the harm is imminent even though, for instance, it may not have effects that will be felt for decades.

The courts have generally adopted EPA's broad interpretation of the word. However, in this case the interpretation of "imminent" under FIFRA appears to be far more restrictive.

I wonder if you've ever asked your staff and your lawyers to look at the agency's approach under FIFRA, compare it to the approach you've taken under other statutes that have an imminent hazard standard, and, if you haven't, whether you would please consider doing that now?

Mr. MOORE. I'm not—I don't recall having asked staff to take the broader look as far as the comparative look across statutes. I certainly would be glad to do that and report back.

Senator LIEBERMAN. I appreciate that, because Senator Reid referred to the growing course of concern not only among the consuming public, but among the apple growers themselves about Alar. It does seem to me that if you're in a posture where you feel that one interpretation of a law is prohibiting you from acting more swiftly and everybody, including presumably one of the targets of your enforcement, is saying, "Please do it," then maybe it's time for another look to see whether you can try to push the law as far as possible. I would appreciate your doing that, and please let us know what you conclude.

The other part that troubles me more recently about EPA is the reaction to the early NRDC report and the first "60 Minutes" show at the end of February, and the contrast in the estimate of what the risk from Alar was, the whole question of residue.

I recall we had some charts earlier today that—in the first reaction the statement was made that 95 percent of the apple crop was not treated in 1988 with Alar. Now more recently—I think in your prepared testimony today—the number used is that 5 to 15 percent of the apple growers are not using—are using Alar. Of course, apple growers could be a much larger percentage of the crop, whereas all of the other independent studies that we've seen quoted range from a low of about 20 percent to a high of over 50 percent.

My concern here is that this variance of numbers and the appearance that EPA was trying to reassure the public about the scare without enough justification ultimately not only was wrong, but will undermine the credibility of EPA in the future.

I wonder if you could just go back now and tell us, how did you arrive at the original 5 percent figure?

Mr. MOORE. Mr. Chairman, numbers of this sort, whether with Alar or any other pesticide, are always going to be crude estimates as long as we have the means available to us that we currently have in order to ascertain them.

Our estimates basically are from reports of sales that are filed with the agency by registrants on a periodic basis. In this instance, in addition to that type of information which is fairly gross as far as numbers are concerned, we also went to two marketing services and tried to get the benefit of their best estimates as to how much has been used. We also relied on comments that had come from the field such as cooperative extension agents or people of that sort.

On the basis of their judgment was where we came up with the original estimate. I believe——

Senator LIEBERMAN. If I may, let me just stop you there.

Mr. MOORE. Yes.

Senator LIEBERMAN. So it sounds like you got the information from the registrant which in this case would have been Uniroyal. Tell me more about the marketing services. Did they go out and actually test apples or what do they do?

Mr. MOORE. No, they basically are the types of people who come up with estimates as to pesticide usage, volume of usage and where it was used in any particular year or any particular period of time.

The other ones, of course, would be more of an anecdotal nature—when we went to cooperative extension agents or State extension agents to get such information.

Indeed, I think events have indicated, subsequent to our original estimates, that, indeed, rather than down at 5 percent, I understand we're now closer to 15 percent. Certainly our estimate was low. Our number is coming up.

Senator LIEBERMAN. Yes.

Mr. MOORE. And I agree with you, it's not something that I think serves the public well as far as instilling in them any confidence in the agency's numbers once you get beyond these types of things.

We probably should have been more emphatic about the softness of the data by which we derived our estimate.

Senator LIEBERMAN. I appreciate your answer because it does seem to me that at a time when there was a real outbreak of anxiety in the public, you came forward with a number that was reassuring but ultimately to me it doesn't seem that it was based on much independent evidence, respectfully.

Does EPA ever test independently in these cases? For instance, several of the independent groups, Consumers Union, NAS, and of course the "60 Minutes" operation last night that we saw, apparently went out and took apples off the shelf and tested them. Do we ever do that?

Mr. MOORE. Traditionally, if we would want information on residues that are in a particular crop, we would either do one of two things or both. We would ask FDA to use some of their surveillance capabilities to get the information for us and share it with us, or the second thing we would do is to ask a registrant to generate such information and then we would have a strong oversight.

It would be uncommon for us to use our own resources, our own laboratory resources, for example, to analyze—do analyses such as these.

Senator LIEBERMAN. Are you aware that—I have a copy of The Washington Post from Wednesday, March 15, in which there's a small note indicating that "U.S. Food and Drug Commissioner, Frank Young, said traces of the chemical Alar were found in half the apples tested by the Government although he does, in fairness, say that at levels well below those considered a health hazard." Are you familiar with that number?

That's pretty simultaneous with the 5 percent report that EPA first gave.

Mr. MOORE. To my knowledge, the main source of data that EPA—I'm sorry, the main source of data that FDA generated, as it relates to Alar on apples, came in 1986 which would be a significant reflection of what was used in 1985 on the apple crop.

It was in that time frame that FDA did a significant amount, an extensive amount of sampling to get a sense as to how much was treated and what were the levels. Any data from FDA subsequent to that period of time I would say would be modest as far as numbers of samples.

I would assume—and this is off the top of my head—that what Commissioner Young would be referring to back in March would have been the primary data set which would reflect not current levels or what was used in 1988, but would be more likely to reflect what was used back in 1985 or 1986.

Senator LIEBERMAN. It is misleading to me that a day before EPA issued the statement saying that the problem was only on 5 percent of the apples that the article says more than half.

Dr. Moore, at any point in that early period after the original NRDC report and the "60 Minutes" show were you or others in the agency under pressure from people in Government or the private sector to underestimate or play down the potential threat from Alar on apples?

Mr. MOORE. We certainly were given the opinion of a variety of people as it relates to Alar on apples, ranging from consumers, mothers, parents, to producers, shippers, growers. I think it would be safe to say that we probably heard from all spectrums of society

as it related to it, and all obviously representing a different point of view as to what should or should not be done.

We certainly were of the opinion that the public overreaction to the health risk of Alar was that, an overreaction. Based on our own opinion, we were willing to try to convey to the public a more reasoned perspective as to what the degree of risk may be.

I realize that's also a very difficult limb for an agency like EPA who, on the one hand, is saying, "I'm concerned enough about this product; I want to take it off the market," but then also to be in the circumstance of having to say, "Not to worry" at the same time. You're trying to send two what appear to be diametrically opposed messages at the same time, and my sense is, whether it's me or anybody else, one's not going to be very successful trying to send what appear to be diametrically opposed messages almost at the same time.

Senator LIEBERMAN. I agree with you, and I think that's the problem and the result. Unfortunately, again there has been an impact, a negative impact, on EPA's credibility. I certainly wish that at the outset there would have been some independent testing, because people look to the Government to do that kind of testing. We shouldn't have to wait for independent groups like Consumers Union or television operations like "60 Minutes" to do it.

Mr. Chairman, I appreciate your tolerance. I've gone over the time allowed. I have other questions, but I'll wait until we come back.

Senator REID. Senator Warner?

Senator WARNER. Thank you, Mr. Chairman.

Let me pick up on my distinctive colleague's line of questioning here. You heard, as you said, from all spectrums of society and there was a general overreaction, but do I understand that the agency has now made a determination that Alar should be banned? There was some report of that in the press. Could you clarify that?

Mr. MOORE. Senator, back in January we said that the data we had in hand led us to conclude that, based on new information, not old information that was discredited several years ago, but based on new information, that we thought that the risks outweighed the benefits of continued Alar use and we were going to start the formal process resulting in its being removed from the market.

What I signed Friday was the document, the legal document that will appear in The Federal Register notice that will commence that formal process.

Senator WARNER. Given the present state of the law and regulation, that process could take as long as what period of time?

Mr. MOORE. Well, our estimates are that the final decision on Alar in this instance probably will come out at the turn of the year.

Senator WARNER. Now wait a minute. "Turn of the year"?

Mr. MOORE. In 1990, early 1990.

Senator WARNER. Now that's only eight or nine months.

Mr. MOORE. Correct.

Senator WARNER. Where did I get the figure that it would take 18 months just——

Mr. MOORE. When we announced in January the action that we have now formally taken, we were estimating somewhere around

15 months. Our estimates, again, are somewhere around early 1990 that the information will be taken——

Senator WARNER. I accept your representation. Then should there be legal proceedings, which various parties have a perfect right, that could further prolong the period; is that correct?

Mr. MOORE. Correct.

Senator WARNER. So we're looking at a minimum of eight or nine months, and within that period, as an apple grower myself, August—I think July, August is the time when you use Alar. So there would be some decision points for a lot of people in the orchard business to use or not use Alar this summer.

Assuming that it's perfectly legal to use it, some may use it and then we have this cloud cast over the whole apple crop that's coming to the market this fall.

I mentioned this morning that perhaps Congress should look at the option of taking some legislative action to take this particular type of chemical and ban it now. I said, very carefully, that, speaking for this Senator, I would consult with a wide range of people before I took any initiatives.

What would be your reaction to Congress, given the complexity of Alar, the fact that it's a lost cause, you made your initial determination, you've got all of this—and I use your words, you've heard from all spectrums of society and there's public overreaction—maybe we'd better do something swiftly to try to let us then in a more even and methodical way address the overall problem with pesticides and not have this great uncertainty and really harm being inflicted on the public, not only the consumers but those engaged in orchard work and right on down through the chain.

What would be your reaction if I were to ask, and I now ask you your advice?

Mr. MOORE. The generic response to your question is that I do not think it's good public policy for Congress to be enacting chemical-by-chemical specific legislation. That's not certainly a new statement on my part. I made the same statement to this full committee about a year and a half ago when it moved forward legislation on tributyltin.

You continue to treat symptoms, but won't seem to get to the root of the problem.

Senator WARNER. And would you consider this possibly an exception to your generic position? And I respect that. You're given a responsibility under the law and you're doing the very best you can, but I ask you, given the extraordinary circumstances that now confront this one particular chemical, would you think this is—should be considered as a possible exception?

Mr. MOORE. I think if one were to enact such legislation, it would be representing a politic sense to solve a problem of great concern and to large segments of the population. It would be an action that I would understand. I could reconcile it in my own mind. Still, I'm not sure that it's good public policy——

Senator WARNER. It may not be good public policy.

Mr. MOORE [continuing]. If perpetuated, and that's why I raised the tributyltin example. That should be the second example that I can think of in 15 months where we continue to do chemical-specif-

ic legislation without getting to the root problems which I think are in the statute.

Senator WARNER. Doctor—can I have just another minute here?

Senator REID. If the Senator would yield just one second——

Senator WARNER. Yes.

Senator REID. But you're going to give us the——

Mr. MOORE. I could even tell you what they were right now if you would ask me, Senator.

Senator REID. No, I mean the formula for doing it.

Mr. MOORE. I could give you those right now.

Senator WARNER. Well, I was going to move along here with just one or two questions.

Senator REID. Please.

Senator WARNER. So you think that, given the public problem out there and the uniqueness of this situation, and to relieve the tensions, particularly in the young mothers who are struggling with the question on the children, and also the contingency, as we say in the military world, of this thing also spreading into other areas as a consequence of the same use of the basic chemical, this concerns me. I appreciate that.

I will consult with you and others further on this, but I would come back, then, to the FIFRA law. What sort of fixes would you put in it?

Mr. MOORE. Well, to address the concerns that we have, once the agency makes a determination that action should be taken against an existing chemical, I think we should have the ability to move forward and effect cancellation to bring it to closure, if you will, short of the Federal court, which I obviously have no control over, in a reasonable period of time. To go through a process which allows for notice and comment that might be a year or a year and a half or 15 months' duration, which is the cancellation process as we described it, is probably entirely too long in the eyes of many, but then to also have a process whereby you can have a hearing subsequent to that determination which could last several years, if history is our guide, while the product stays on the market, I think reduces the agency to a perception on the part of the public of not acting in their best interest when in fact it's stuck by the statute.

Senator WARNER. That was the problem that I addressed earlier this morning when I said there's some blame to be spread around, the Executive branch, but it's also on the Congress. I've only been a member of this committee three years, and I'm not suggesting my predecessors should have taken the initiative, but, anyway, the fact is the law is basically deficient.

Have you and the Administrator contemplated formally submitting to the chairman and members of this committee a series of recommendations as to how to fix this act?

Mr. MOORE. We have had discussions within the agency and are now having discussions within the Executive branch that basically focus on three changes to FIFRA that are germane to the issue that is exacerbated by the Alar controversy.

One would be to eliminate that middle step of the administrative hearing. Notice and comment rulemaking, when a decision is reached, if you still think that you are aggrieved, go to the Federal courts; eliminate this middle step.

Secondly, maybe a more permissive possibility of invoking suspension than is in the current statute, putting a little bit more discretion on the part of the Administrator as to when that could be utilized.

The third thing which is maybe more holistic is maybe a sunset provision for the registration of any pesticide. Once the agency decides you can go on the markets, that's fine, and let's just pick a fixed period of time. I don't care what that is, but it's not measured in weeks or a couple of years, but say ten years or something like that, at the end of which, if you want to continue to market your product, you have to secure a new permit, so to speak.

Senator WARNER. I thank the Chair, and I thank the witness.

I think we are, indeed, fortunate to have you. You have been in the agency since 1983?

Mr. MOORE. Yes, sir.

Senator WARNER. You've had a long and distinguished career of public service.

Mr. MOORE. Thank you.

Senator WARNER. I hope you continue.

Thank you very much, Mr. Chairman.

Senator REID. Mr. Moore, I know that we always find trouble having you respond to this question, "you" meaning people who don't set the policy of your agency. Do you currently have the staff to comply with FIFRA amendments, FIFRA law basically?

Mr. MOORE. No, sir.

Senator REID. Okay. You're the first person all year I've asked that question to that's answered it honestly. They say, "Yes," "Well, maybe," "I don't understand the question." I appreciate that because, had you said anything different, I wouldn't have believed you because I haven't believed the other witnesses who have come before here and mealy-mouthed that question.

You're working under a tremendous obstacle when you have enough people to do the work; isn't that right?

Mr. MOORE. Yes, sir. When I was thumbing through the book here when Senator Lieberman recited his questions, there was a table that caught my eye this morning. That was the comparison of EPA's pesticide budget from 1979 to 1989.

Senator REID. Tell us——

Mr. MOORE. I don't remember the exact numbers, but while we roughly have the same dollars available to us in 1989, not adjusted for inflation, but just real dollars compared to what the agency's budget was in 1979, despite increases in our personnel budget, we still are not at the level of manpower for the pesticide program that the agency had in 1979.

Now FIFRA 1988 does provide a significant amount of resource for us to be able to meet the deadlines implicit in the re-registration process. We have the challenge, obviously, of hiring up once those resources are available. That's going to be possibly problematic because of the long need for types of skills that are needed to get the job done and, frankly, inability on good days for us to be able to attract the quality of person that we need to begin with.

Senator REID. How many toxicologists are on your staff?

Mr. MOORE. I don't remember the exact number——

Senator REID. Give me a rough estimate.

Mr. MOORE. I think, out of the—I think it's 200-and-some-odd of the 500-odd people in the pesticide program have scientific background of one sort or another.

Senator REID. How long have past cancellations taken?

Mr. MOORE. Upwards of six to eight to nine years, more recently probably more in the area of three to four years.

Senator REID. How long did it take to cancel chlordane?

Mr. MOORE. Chlordane was initially looked at by the agency back in the early seventies, and all agricultural uses of chlordane were cancelled in the mid-seventies, as I recall.

There was a public period of three or four years. The remaining use of chlordane, which was for termiticide use, was eliminated about a year and a half ago.

Senator REID. What about our imported products? You were present this morning when Ralph Nader and others talked about the dangers of imported food. We ban chemicals here; we continue to manufacture them; we send them other places and they use them and then we get the food back with these pesticide residues on them; isn't that true?

Mr. MOORE. Now part of it is true. It does not necessarily have to come the full circle. You are quite correct that a product that has been cancelled for use in the United States can be manufactured and exported to other parts of the world. That does not automatically translate into the fact those pesticides are going to come back into this country as residues, say, on foods. That can happen. That particularly can happen with some of the pesticides that have a long half life.

What we have attempted to do is to reduce the tolerances on chemicals such as chlordane and things like that to insure that, indeed, we do not permit current uses of chlordane, say, in a Central or South American country, which is where a lot of our winter fresh food comes from, while it's banned in the United States, the outcome being that the dietary risk certainly remains the same.

Senator REID. Is the administration going to request the resources provided in FIFRA 1988?

Mr. MOORE. Yes, sir. The way we interpret what was in that statute is that we do not have to come up and ask for an annual appropriations. The re-registration fees go into a special account maintained by Treasury, and we can draw against that account without having to seek appropriations on an annual basis through Congress. We certainly have to periodically seek access to that money from OMB.

Senator REID. There is a real problem that we have with the Scientific Advisory Panel. I have a long list of questions in writing in that regard. Suffice it to say that from what's going on in Government today and in recent years, we not only have to do what is right, but what appears to be right.

At the very least, the Scientific Advisory Panel, as it has been established, hasn't really looked right because we've had people on that panel who have worked, for example, for Uniroyal who sells Alar and other examples.

Is there anything to prevent the Administrator of the EPA from appointing people on the Scientific Advisory Panel who would be, for example, pediatricians, public health officials, nurses, school ad-

ministrators, anyone that would have some knowledge of basic science?

Mr. MOORE. The current statute says that the agency can only select from lists provided to it by the Director of the National Institutes of Health or the head of the National Science Foundation. To the degree that we have those types of professions on the lists of nominees provided to us by the National Institutes of Health or NSF, we could select them.

Senator REID. Yes, but——

Mr. MOORE. Traditionally, the lists that we have gotten are certainly narrower than that.

Senator REID. But, Mr. Moore, there certainly would be no problem if you wrote back and said, fine, we've got this list, but we would like you to include in here someone from this, someone from that. Nothing would prevent you from doing that, would it?

Mr. MOORE. No, we have done it in the past, in fact, in the annual rite of requesting names, to point out the types of skills we think we would need based on the type of skill that may be retiring from the panel.

I think something that may be a problem in this area, Senator, is that that panel is by committee standards and given the breadth of science issues that are associated with pesticide use, may just, frankly, be too small. It's seven members, and seven members aren't very many to cover the types of skills that you might want on an advisory panel.

Senator REID. Maybe we would be better off doing away with it?

Mr. MOORE. I think it would be a mistake to do away with the opportunity, a legal requirement to have peer review opinion available to the agency prior to its decisionmaking process.

Senator REID. Senator Lieberman.

Senator LIEBERMAN. Thank you, Mr. Chairman.

I want to continue this line of inquiry about this Scientific Advisory Panel. Dr. Moore, in the time that you've been at EPA, five or six years now, do you ever remember a case where the Scientific Advisory Panel concluded that EPA had underestimated the risk of a pesticide on an action that it was about to carry out?

Mr. MOORE. None immediately come to mind, Senator.

Senator LIEBERMAN. Do you recall any cases where the SAP, in addition to the Alar case which we're familiar with, told EPA that you were overestimating or were making a mistake in estimating the risk of a pesticide?

Mr. MOORE. Yes, sir, commonly.

Senator LIEBERMAN. Commonly?

Mr. MOORE. Commonly.

Senator LIEBERMAN. Let me take the Alar case and then come back to that. From all that I've read here, the first indications of trouble with Alar—that is, that it might be cancer causing—first showed up in 1973. Staff at EPA began to put this into a special review which was, I gather, an expedited proceeding for getting Alar off the market. There were consultations with the manufacturer that stopped. There was an NRDC lawsuit—this goes into the early eighties—which opened up the process again, and then that began the review which led to the recommendation by EPA staff that the use of the chemical Alar be cancelled.

You had at least 10 years of experience, a growing body of evidence that this chemical caused these, I gather, unusual blood vessel tumors in laboratory animals, and then the Scientific Advisory Panel says wait, and EPA waits.

To me, I wonder whether it in some sense shows a lack of confidence in your own staff. Why would the advice of these scientists be so effective with you?

Mr. MOORE. Senator, first of all, I think the advice that we get from the Scientific Advisory Panel is good advice, and I do think it reflects the norms of the scientific community in large part.

At the same time, I think if one could sit here and fault, if you will, the process leading up to the original recommendation of Alar, I think the agency should be faulted. The agency certainly knew, I would presume that it knew, back in 1978 or 1979 when it first started to look at these studies, that those studies were flawed. They certainly don't come close to meeting the standards of testing that were asked at that time, let alone today.

If there were a criticism that I would retrospectively make on the agency, why didn't they at that time where you had data suggesting a problem demand of the registrant then to redo those studies so that we had good data? For whatever reason, they didn't. They continued to rely on the old studies. It was the composite of the old studies which we admit were flawed in our own documentation, but in the composite we thought indicated a health risk that went forward in 1985 and was criticized by the Science Advisory Panel as far as being inadequate for decisionmaking, because, in their opinion, the flaws in each and every one of those studies were of such a magnitude that one shouldn't move forward.

Now I think in 1989 when we're having new studies finally being done that are coming in showing that you are finding those same blood vascular tumors in mice, that it now lends credibility to the composite findings of the older, flawed studies.

Senator LIEBERMAN. Yes, that's what, again, strikes me as a layman here, that—I'm not a scientist; I can't quibble with methodology, but, contrary to what I think may have been an implication earlier in your testimony, the new evidence doesn't reach any different conclusions. It reaches the same conclusions that were reached 16 years ago, which is that this stuff causes blood vascular tumors in laboratory animals.

Mr. MOORE. Correct.

Senator LIEBERMAN. And, therefore, of course, I wonder why we didn't get to this conclusion earlier and why the Scientific Advisory Panel's reaction was so effective, why it overrode the accumulated experience of your staff within EPA in 1985.

Mr. MOORE. As one who was part of the process that brought it forward to the panel and obviously was part of the process that agreed to basically go along with the recommendations of the panel, I think something that can't be lost sight of is it's a risk-benefit decision that the agency must make.

If you take the risk part of the equation away because somebody says the studies are flawed, you have nothing left but the benefit part of the equation. If we were to move forward in a circumstance like that where the legally-constituted panel of experts advised against the use of such data, I would say that we would be in a

very doubtful legal position if we had been challenged to moving forward. I think that was part of the decisionmaking process.

Senator LIEBERMAN. You indicated a moment ago that you thought the Scientific Advisory Panel represented the norm of the scientific community. What troubles me, as you know, we've found from reviewing the disclosure statements that seven of the eight members were consulting for the chemical industry at the time they made the judgment on Alar. Even if that were the norm, even if their advice was the norm of the scientific community, the natural tendency of an onlooker is to think that it may have been the norm of the part of the scientific community that was consulting for the chemical industry because it's hard to view the council as dispassionate, particularly when two of the members then end up going after they left the panel to work as consultants for the manufacturer of Alar or on behalf of a product manufactured by that company.

Let me just ask you for a response. Do you think it is appropriate that these people on that committee were consulting for the chemical industry at the same time they were advising EPA on chemicals in the food supply?

Mr. MOORE. I think I would assume that in the filling out of their financial disclosure statement at the time that they were appointed that they had identified the fact that they may be a consultant for Chemical Company X or Y, or whatever the case may be. That in itself is not a bar under law from appointing somebody to serve as an expert individual.

I would say, however, that my previous experience has been with other committees as well that a scientist who is sitting on a committee in which an issue comes up in which the chemical company for which they consult makes it or is involved with it, they usually do one of two things or often do both. One, they will announce that, indeed, they are a consultant or have been a consultant to that chemical company whose product is now coming before the committee and they often will refuse to take part in the deliberations.

Senator LIEBERMAN. Our review of the EPA guidelines here say that members of the panel were obliged to recuse themselves on a particular chemical if they had worked for the company that manufactured that chemical during that year. I understand that that's not against the law, but don't you think personally that it undermines the credibility of that review process?

Mr. MOORE. Senator, I think what we're into here is the main issue that is the toughest one in the Government ethics bills of one sort or another or practices, and that is the perception of conflict. I think this is what we're entering into right now.

I guess the counterbalance—and I'm not trying to appear to take sides on it—I think the counterbalance is that if we apply too rigid a standard for somebody to participate on a science peer review board, that you're going to lose probably the best scientists or some of the best scientists that you would like to be active in such deliberations to begin with.

I'm not saying that the current status is maybe the perfect way to do it, but——

Senator LIEBERMAN. Again, you may not be in a position to speak for the agency totally on this, but I really urge you to go back, because there's got to be a lot of good scientists out there, not to mention the pediatricians and public health people that Chairman Reid talked about who would be willing to serve on these panels, and not allow people who are upset by one of their decisions to come back and say you did it because you're also getting money from the chemical industry.

Also, particularly true of those two who went to work—and I'm not going to ask you about that because we've asked the Inspector General to review that—to me, I'm afraid that literally is a conflict of interest when they sat on a particular case—a violation of the law—and then went ahead and worked for those chemicals after they left Government service.

Mr. MOORE. I'll look to that letter. I do know one of the instances that you refer to was under active investigation by the Inspector General and I would have to see the specifics of the other one in order to comment.

Senator LIEBERMAN. I appreciate hearing that.

Again, thank you, Mr. Chairman.

Senator REID. Thank you. We may have some written questions we'll submit to you.

Mr. MOORE. Thank you.

Senator REID. Our final panel of witnesses consists of Mr. John McCarthy, vice president for Scientific and Regulatory Affairs of the National Agricultural Chemicals Association, and Ms. Janet Hathaway, senior projects attorney, National Resources Defense Council.

We have expressed our appreciation to everyone. We do so even more to you; you've had to wait so long, for which we're grateful.

Mr. McCarthy, would you proceed?

Mr. MCCARTHY. Yes.

Senator REID. We would appreciate your limiting opening statement to five minutes.

Mr. MCCARTHY. Yes, I'll summarize the material that we submitted.

Senator REID. Mr. McCarthy, Ms. Hathaway, would you both raise your hands?

[Whereupon, the witnesses were sworn.]

STATEMENT OF JOHN F. McCARTHY, VICE PRESIDENT, SCIENTIFIC AND REGULATORY AFFAIRS, NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION, WASHINGTON, DC, ACCOMPANIED BY JACK EARLY, PRESIDENT, NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION

Mr. MCCARTHY. Thank you for the opportunity to testify on behalf of the National Agricultural Chemicals Association. Needless to say, we've got a vital interest in the subjects of the regulatory process, neurotoxicity, and how carcinogenic risks are handled.

Let me talk briefly about each of those points, the regulatory process first. Obviously, it's been taking a beating and the credibility needs to be restored.

Is the process working? We believe yes. Is it perfect? No. Can we make improvements? Yes. What do we advocate? Basically, two things: implementation of the 1988 FIFRA amendments without a hitch and increased monitoring of the food supply. Let me just talk briefly about these two points.

The main controversy, as you have been hearing, is over the older pesticides. There has been considerable difficulty implementing the reregistration process which was mandated in 1972, and there's enough blame to go around.

However, we believe the program's on track because FIFRA 1988 provided a clear direction, but, more importantly, gave EPA the resources to do the job. We will pay in fees over the next nine years $170 million so that people and contractors can be hired to review the data which in many cases has already been provided and which will be provided over this time period.

Our industry wants FIFRA 1988 to work. We can't afford to fail. There are three other points I'd like to make before leaving this subject.

First, the notion that pesticides registered before 1972 weren't tested, that simply is false. Health and safety studies were done according to the scientific standards of the day. Tolerances were set by FDA under the Food, Drug and Cosmetic Act. Chronic toxicity residue studies and analytical methods suitable for enforcing tolerances were done.

Second, reregistration isn't starting from ground zero. You have heard some statistics on that in terms of 90 percent of the pesticides are in the process of a registration standards data call-ins for 350 food use chemicals. What this means is the upgrading of data is well underway.

Thirdly, the reregistration process must be allowed to work. New legislative initiatives which would place unnecessary burdens on the agency should be avoided. This is a very delicate process that we're going through here now.

What about monitoring of the food supply? We've stated on a number of occasions before Congress and others that increased appropriations be given to FDA to step up their surveillance program. FDA is doing a good job under enormous resource constraints. We believe, however, that confidence in that is utmost and stepped-up surveillance is a critical part of improving such confidence.

Let me now turn briefly to the issue of neurotoxicity. EPA does require tests for delayed neurotoxicity with organophosphorates insecticides. This is required for other compounds where there's reason to believe that they have a direct effect on the nervous system. I might also add FDA required these tests in the 1960s.

The issue has been raised as to whether or not other kinds of tests should be done. The NACA supports additional neurotoxicological and behavioral effects testing as a legitimate component of the requirements for re-registration and registration. We supported amendments in 1986 and 1987 to FIFRA to this effect. While these weren't passed, we still support that principle and have stated so at the FIFRA Science Advisory Panel on neurotoxicity in October of 1987.

We have outlined some details of what that testing strategy ought to be in our written testimony. We understand EPA will be releasing guidelines this summer for public comment and further SAP review. We encourage that process to continue.

But we would like to end with this last point: that current testing is not devoid of observations which signal neurotoxicological or behavioral effects, but a more systematic system of observations could be added to the current testing procedures as outlined in our testimony.

Now turning to the carcinogenic risk of fungicides, the issue of fungicides, as you've heard earlier today, was highlighted in the 1987 report of the National Academy of Sciences. To say that this information in this report has been abused is an understatement. The report was a policy document and not a risk assessment document. The chairman and members of the NAS committee stressed this on numerous occasions, that the numbers in the report should be looked upon not as real risk numbers, and the report also stressed this.

The main message of the report was that there should be a consistent negligible risk standard applies to oncogenic pesticides on both raw and processed foods. They rejected the notion of a zero risk standard which is now stipulated by the Delaney clause.

Fungicides were highlighted as a group which should receive priority attention to this negligible risk standard approach, and we supported that recommendation. So what's happened since then? As you heard, on October 19 of this past year, 1988, EPA published their policy for implementation of negligible risk recommendations contained in that report. The policy has recently been applied—which we incidentally support—the policy has been applied to the fungicide Captan. Its application to the EBDC fungicides maneb, mancozeb, metiram, and zineb is due this month. It's also noteworthy that the fungicides Captafol and Folpet on that chart are no longer used on food crops.

So what these actions are telling us with regard to the fungicides and the NAS report is that the process is working.

Mr. Chairman, we thank you for the opportunity to testify and would be happy to answer any questions.

Senator REID. Ms. Hathaway.

STATEMENT OF JANET S. HATHAWAY, SENIOR PROJECT ATTORNEY, NATURAL RESOURCES DEFENSE COUNCIL, WASHINGTON, DC

Ms. HATHAWAY. Thank you, Mr. Chairman.

Thank you very much for convening this hearing on such an important issue as the risk because of pesticide residues in food. I'd like to summarize my statement and submit for the record the full statement.

The statement that I've presented to the committee does not give you one important point, and that is that the Natural Resources Defense Council feels compelled to file a lawsuit against EPA for its failure to immediately suspend, to ban as of today, Alar in our food. The reason we feel compelled to do so is that the risk estimates that EPA itself has identified with this chemical are such

that, even if we just accept EPA's own numbers, that constitutes an imminent hazard in our view.

We feel that it is arbitrary and capricious of the agency not to use their imminent hazard authority. Failure to use that imminent hazard authority means that not only are people continuing to be exposed to this pesticide, but the apple markets are going to continue to suffer because people will not have confidence that they can start eating apples and apple products again because they will not know what apples have been treated and what apples have not.

The best thing that EPA can do for apple growers, for consumers, for public confidence being restored in the food supply is to ban this chemical as of today. We feel compelled to try to prod them in that direction.

Recently the media has been focused on disagreements between NRDC and EPA, but I think it's very important for this committee to note that there are large areas in which we are in agreement. In February of this year EPA announced that Alar's breakdown product, UDMH, posed a very significant cancer risk. Their estimate at that time was that the cancer risk from Alar was 45 times what EPA says is an acceptable cancer risk, a risk of 1 in a million.

They've revised that number and, as of this week, they're saying that the risk from Alar is 49 times that acceptable risk level of 1 in a million. That's supposed to give you an estimate of the magnitude of the risk for the average person in the population. NRDC did not feel that that was the only matter at issue because children are heavy consumers of the products that are treated with Alar. We studied children's exposure, pre-schoolers' exposure, and found that the likely range of risk was 240 times what EPA says is an acceptable risk level.

By that, we mean that children eating what is average for a preschooler will be experiencing a risk that is 240 times what the Government says is a reasonable level of cancer risk. We don't really think that the disagreement should prevent action. Whether it's 49 times or 240 times an acceptable risk level by EPA's own admission, this chemical ought to be out of our food supply and it ought to be out now.

Our risk assessment was not based on spurious or crazy assumptions such as the apple industry has suggested. We've never assumed that people eat 28,000 pounds a day of apples. In fact, our risk numbers are based on the assumption that children eat 1 ounce of apple and 2 ounces of apple juice per day. That is the average that USDA calculates.

We also did not assume by any means that Alar occurs at the legal limit. That is not how we would perform a risk assessment. What we did instead was to look at Uniroyal's own data about how much Alar remains in our food supply. We calculated the risk just based on UDMH, this breakdown product. We assumed daminozide, for purposes of this calculation, was no carcinogen at all. That's been in dispute. We just looked at the UDMH risk.

UDMH, the breakdown product of Alar, occurring at parts per billion—ranging from approximately 1 to 100 parts per billion, depending on the commodity—being eaten at levels that children actually routinely consume results in a risk of 1 child out of every 4,200 developing a cancer just from their pre-school years' exposure

to this chemical. If that is not an imminent hazard, I don't know if EPA would be prepared to declare any carcinogen an imminent hazard.

EPA also said that 5 percent of the apples were treated with Alar. We've heard a lot of discussion about why that figure is probably incorrect. Thirty-eight percent of the apples studied by the Food and Drug Administration, which is charged with monitoring our food supply, were found to contain levels of Alar in this year.

CBS said that around 32 percent of the apples had Alar at levels that would indicate use in the current growing season. Consumers Union found 55 percent at levels that would indicate use in the current growing season.

One point that I'd like to raise with the committee is the importance of the issue that you all have identified of the independence of the Scientific Advisory Panel. There is no question but that reasonable scientists can disagree, can come up with different risk estimates. This is an imprecise science. It is absolutely essential to the integrity of this program that the people who are rendering judgment on these chemicals have no ties to the chemical industry—none. It may not be illegal, but it is highly improper that the people who are sitting in judgment on these chemicals have a potential interest in further employment with the chemical industry down the road.

I entirely agree with Senator Lieberman's statements that we do have to look at pediatricians, public health officials, and other people with some independence from the chemical industry in rendering these judgments. It may not be possible to find anyone who is truly objective, has no predisposition one way or another on chemicals, but it is most certainly and categorically possible to find people who are not receiving money from the chemical industry to be on these boards. Indeed, we must do that.

Thank you very much. I'll be happy to respond to questions.

Senator REID. Ms. Hathaway, your prepared statement is outstanding.

Ms. HATHAWAY. Thank you.

Senator REID. There's a tremendous amount of work contained in it, and that statement along with the one of Mr. McCarthy will be made part of the record in their entirety.

Where did you get the information that the International Apple Institute claims that a person must eat 28,000 pounds of apples per day to approximate the UDMH exposure levels?

Ms. HATHAWAY. Well, the International Apple Institute took out full-page ads shortly after the first "60 Minutes" report. I believe it was a week or so following the first "60 Minutes" report. In that advertisement it suggested that the 28,000 pounds a day were necessary in order to approximate the risk that was posed by the chemical to laboratory animals.

Senator REID. Mr. McCarthy, on page 2 of your statement you describe the activities of public interest groups as "toxic terrorism." Is that to say that the public should not be concerned about pesticides in food?

Mr. MCCARTHY. No, that's not to say that they should be concerned about the way in which the pesticide residues in food are regulated. I just think that in this situation here this last couple of

months with the apples and the issue of pesticides in fruits and vegetables, it's simply gotten out of hand.

Senator REID. But what——

Mr. MCCARTHY. Statisticians have been—"My statistician has been better than your statistician," and I just think it's reached proportions of taking apples off the shelf and out of school lunch programs, and so forth.

I can understand all of the mixed signals that were going on out there, but I just think there was a lot of fueling of those flames unnecessarily.

Senator REID. Don't you think that Uniroyal would be well served and would serve the American public, the apple industry, and others by just saying, "We're not going to sell Alar anymore."

Mr. MCCARTHY. I would prefer that you pose that question to the Uniroyal Chemical Company.

Senator REID. Fine, but you are a representative of the chemical industry. What's your opinion? The apple people are upset, the consuming public, who obviously aren't buying apples, are afraid to drink apple juice. It seems that we have this cloud around here. I don't know who other than Uniroyal wants to sell Alar.

Mr. MCCARTHY. I can give you my own personal opinion, and not——

Senator REID. Please——

Mr. MCCARTHY [continuing]. Not speaking for the association or anything like that.

Senator REID. Please do.

Mr. MCCARTHY. But I would have handled this thing a whole lot differently back in January myself personally.

Senator REID. Tell me what you would have done.

Mr. MCCARTHY. I would have taken tougher action on Alar.

Senator REID. Against Alar?

Mr. MCCARTHY. Yes.

Senator REID. Okay. Then I assume, speaking for yourself and not the industry, wouldn't we be better off that Uniroyal, who makes things other than tires obviously, wouldn't we be better off if they just suspended the sale of Alar?

Mr. MCCARTHY. It appears that that would be the case, given the political climate. How we got there, we can debate that. It's another kettle of fish. I don't think—I think that we got to this point by a series of events that I do feel bordered on toxic terrorism, but given where we're at today and all of those mixed signals, and so forth and so on, it doesn't seem to be in anybody's best interest to continue the debate.

Senator REID. Ms. Hathaway, since you're one of the toxic terrorists, could you tell us as to whether or not you feel that Uniroyal should suspend the sale of Alar?

Ms. HATHAWAY. Categorically, yes, I think that Uniroyal must suspend the sale of this chemical if we're going to get back on the road to people eating fruits and vegetables that are very nutritious, very wholesome, and should not be contaminated with a dangerous, cancer-causing agent.

I would like to respond for one second to the notion that we're toxic terrorists. The Natural Resources Defense Council has worked for many years on pesticide issues. We've had people who

have studied many different kinds of problems surrounding the pesticide issue from the residue levels in food to worker exposure to groundwater contamination. We've labored very long and hard to identify facts and to debate these issues on the merits.

I think it is the case that people are more concerned than they have ever been about pesticides in food, but it is not because we have used hyperbole. We've not exaggerated. We have stuck to the facts as we know them, used risk assessments in a conservative manner, and I think that the concern that has been raised in the public's mind is entirely justified by the very scanty degree of regulation that's occurred on these chemicals.

It's because EPA has not kept up with the science in its regulatory program, it has not consistently ratcheted down uses of chemicals when it learned that these chemicals are dangerous, that the public is alarmed, and is justly alarmed, about pesticide use in America.

Senator REID. Senator Lieberman.

Senator LIEBERMAN. Thank you, Mr. Chairman.

Ms. Hathaway, I want to go back to some of the discussion about the Scientific Advisory Panel. I recall that in the early eighties, after a special review process had begun, the EPA entered into negotiations with Uniroyal and then stopped the process. It was then an NRDC lawsuit that opened it up.

What happened then? I keep trying to answer this question: here we are 16 years after the first evidence that Alar might cause cancer and we're still fighting over whether it should be on the market?

Ms. HATHAWAY. Well, in the eighties we have not seen a dramatic change in the pesticide program, but in the seventies there were some even worse problems in that we couldn't even find out what discussions were going on between the chemical companies and EPA. There were secret negotiations that occurred. There were meetings that we were not invited to, that we could not attend, which would decide the fate of various chemicals.

We felt that that was a terribly improper process, brought suit, and, as a result of our suit, got a settlement that was to guarantee that there would be open meetings in which these chemicals would be discussed.

That hasn't solved the entire pesticide problem by any means, but it at least allows some sunshine into the process and allows some criticism to occur from the public interest community.

Senator LIEBERMAN. So actually you don't really know why EPA at that time stopped its special review of Alar because those were secret meetings? Those were private meetings?

Ms. HATHAWAY. That's right. We weren't allowed to be part of those deliberations, so we have no idea whether there were solid grounds or completely improper grounds.

Senator LIEBERMAN. Or whether it was just influence from the manufacturer that stopped it.

Ms. HATHAWAY. Well, the appearance is certainly very bad and we felt that at the very least the appearance of some agreement between the chemical industry and EPA had to be eliminated.

Senator LIEBERMAN. Okay, but then we do know that in 1985 the EPA staff began a cancellation or it was recommending cancella-

tion, and the Scientific Advisory Panel stopped it. I was interested in Dr. Moore's testimony that he told us that he couldn't remember a time when the panel had ever told EPA that it was underestimating the risk of a pesticide but could remember several where the panel had said EPA was either overestimating the risk or that it's methodology was wrong.

Now is the panel there to stop EPA from acting or do you believe that they have genuine scientific concerns about what EPA has wanted to do, when it has wanted to do anything?

Ms. HATHAWAY. Well, I think that it's important to focus on an actual case that we've all been thinking about, and that's Alar. If we think about what the Scientific Advisory Panel said in 1985 in Alar, I think it gives me pause that EPA would use their statements, the Scientific Advisory Panel's statements, to reverse its intent to cancel.

Let me read really briefly from what the Scientific Advisory Panel said when they deliberated about Alar. They said, "The Toth Alar studies"—these were studies performed by a doctor named Toth—"do present concerns over the potential oncogenicity of daminozide. However, none of the present studies are considered suitable for quantitative risk assessment. Given the fact that the Toth data has been available for eight years, the panel does not understand why EPA has neither requested nor the registrant initiated in a more timely fashion additional oncogenistic testing."

Here was the Scientific Advisory Panel itself castigating EPA and Uniroyal for failure to study the chemical adequately. I would think, in response to that, a reasonable thing to do with the chemical would be to cease its use during the pendency of further study.

There has not been adequate study of the chemical, the Scientific Advisory Panel says, but that does not warrant allowing the continued use of the chemical in food.

Similarly, the Scientific Advisory Panel had statements about the risk from the breakdown product, UDMH. They felt that there was one scientific study that was suitable for quantitative risk assessment that had been performed by looking at the inhalation or the breathing exposure to this chemical.

So it's not as though the Scientific Advisory Panel categorically rejected that there was any evidence of a problem from daminozide. The policy issue that arises from the Scientific Advisory Panel's recommendation is, What do you do when you know that something is bad but you are not quite sure how high the human risk is? Do you allow people to continue to be exposed to it while you try to gather more data about the human risk or do you say, enough already, people have been exposed for many years to this chemical; let's cease the exposure while we study it further?

Senator LIEBERMAN. There's no question—I don't know what the experts would say, but the average American would certainly say, "Protect us from that." That's just what was not done.

One thing that's come up a few times as we deal with Alar is the question of exports or imports. In this case I'm concerned about imports. Let's say all that we would wish happened and use of the chemical on apples in the United States stopped, do you have any knowledge of whether it would still be coming into the United States on fruit, apples particularly, that we imported?

Ms. HATHAWAY. It's very likely that there would be continuation of exposure to Alar, for the simple reason that more than half of the apple juice concentrate that is consumed in this country comes from abroad.

I spoke with a Uniroyal representative who said that marketing has been very intensive in other countries, in Argentina, other South American countries that are apple producers, and also in the European Economic Community, of Alar. So I think that is extremely important that we send— "we" the United States, EPA— send a categorical message to these other countries that we deem Alar too hazardous to use on our food.

A suspension action is likely to result in other countries saying this must be a serious health threat or the United States wouldn't have acted in this emergency fashion, and hopefully that would mean that other countries would stop use of the chemical as well.

But if we allow a laborious cancellation process to take many years, I think we can continue exposure through our importation of these foods that have been treated.

Senator LIEBERMAN. Did you just say that half of the apple juice coming into the United States is from foreign-grown apples?

Ms. HATHAWAY. Half of the apple juice concentrate.

Senator LIEBERMAN. Concentrate? Okay.

Ms. HATHAWAY. Yes, comes from abroad.

Senator LIEBERMAN. Okay. Mr. Chairman, I have a couple more questions.

Senator REID. Go ahead and ask them.

Senator LIEBERMAN. Thank you.

One more for you, Ms. Hathaway: I didn't get a chance, unfortunately, to ask Dr. Moore, but let me just ask you from your perspective. I'm troubled, just to show that this is a broader problem which we obviously have heard all day, about the EPA decision on Captan. We heard testimony this morning that it is one of the more dangerous of the fungicides in use. EPA comes along and, for some reason, bans it on either minor fruits and vegetables or major ones on which there's not much use and continues to leave us, it's my understanding, exposed to a fair amount of use on commonly-used, widely-used fruits such as strawberries, cherries, or grapes.

What happened there and how do you and the people at NRDC react to that decision?

Ms. HATHAWAY. I consider the Captan decision to be a major breach of faith with the public. What it has done is identified a very serious health risk, identified where the exposures are coming from, and has basically skirted the issue of changing the use where the exposure is greatest and ensuring that legal limits are safe on all the foods that we do eat in high quantities.

It's easy to eliminate a legal limit for quince. I don't think a lot of people are going to even notice if quince is out of their diet. It was never in my diet. I think that the same goes for leeks.

What we need to do is set a tolerance level that we know is going to be safe. It doesn't make any sense to say, "We don't think the risk is too high because the tolerance level is never being exceeded." If we know that the legal limit is very different from the actual residue level, we ought to set the legal limit down where the

actual residues are, so that we can ensure that all growers are using the chemical safely, prudently, minimally.

What happened in Captan indicates that the agency isn't willing to bite the bullet here and say to the apple growers or the strawberry growers, "We have to insure that the Captan use on these products stays at the levels that other growers are able to occasionally achieve or maybe routinely achieve."

We don't want growers to think that it doesn't really matter whether you exceed the level that other growers are achieving.

Senator LIEBERMAN. Again, I regret that I didn't ask Dr. Moore this, but has EPA been called to answer by you or anyone else as to why they made this decision which seems so off, so nonsensical?

Ms. HATHAWAY. Well, we think that the appropriate reaction to the Captan decision is to sue EPA again with regard to the Delaney clause. I'm sorry that we're forced into litigation constantly. We'd prefer to work these things through without litigation, but what has happened is EPA is saying that it will allow a negligible risk of pesticides in our food supply even though the statute, the Food, Drug and Cosmetic Act, says that for processed foods there cannot be any level of a carcinogen.

We feel that if the agency is serious about changing the law, they ought to come to Congress, come to you, suggest how the law ought to be changed. We don't think that they ought to unilaterally reinterpret a statute that is designed to say, "no carcinogens in the diet" to somehow be read as, "some carcinogens so long as that carcinogenic risk is, in our view, negligible."

This is the first—the Captan decision was the first instance of applying their negligible risk policy. It was a ludicrous decision, in my view, even if you were to buy their interpretation of the law, because it is not insuring that we do keep the legal limits at a level that will, in fact, provide a negligible risk for our whole population.

Senator LIEBERMAN. Thank you.

If I may just ask one or two brief questions of Mr. McCarthy: there are points in your testimony—on page 9 you say the process is working—where it seems that you're saying that changes in the law are not required in spite of the fact that we've heard so much testimony about the shortcomings of the system today.

I do know a couple years ago, from the record, that your association did, however, support amendments that would have shortened the time that it takes EPA to conduct the special reviews and associated appeals down from about ten years now to two to four years.

Do you still support—am I correct in that—do you still support those changes? What other changes in the law does the industry think might be required?

Mr. EARLY. Apparently, Dr. McCarthy wants me to respond. I should be sworn, Mr. Chairman, before I answer the question.

[Whereupon, the witness was sworn.]

Mr. EARLY. My name is Jack Early. I'm the president of the National Agricultural Chemicals Association.

The reason I was not your lead witness here today, I was under the impression it was more scientific. So I let the scientific people participate here. I have been waiting here to answer a question or two, of course.

Yes, we did have a very substantial FIFRA revision bill in place that we negotiated with the environmental community, and we came within hours of passing that piece of legislation. I think, unfortunate from our standpoint and the environmentalist standpoint, we did not deal with that issue because it dealt beyond what we're talking about today, also into groundwater issues. It dealt with a lot of critical issues in our industry and in the environment. That's very disappointing we didn't do that.

Do we still support that position? Yes, we still stand behind that piece of legislation. We would be delighted to support it.

Senator LIEBERMAN. I appreciate it. May I say that you can hear today—and, again, I know the chairman of this subcommittee intends to hang in there on these issues—that we're going to do all we can to see if we can improve the process. We, therefore, invite your cooperation and your ideas about how we might do that.

Mr. EARLY. May I just add one other, since I've been waiting to say this? You'll pardon me.

I think that Dr. McCarthy has pointed out a couple of areas—and I think you heard it from Dr. Moore also. We went through the process in the last Congress. We passed FIFRA 1988. I think it's beginning to move forward.

Also, we have legislation before this body and the House, also you heard this morning, I believe, to begin to deal, to dovetail these two statutes between the Food, Drug, and Cosmetic Act and FIFRA, which really needs to be done.

In fact, what that's going to do is carry out the mandate almost from the National Academy of Sciences to address this minimum risk situation. I think the process is underway and it may not be moving fast enough for some people, but at least it's underway.

Mr. MCCARTHY. I just wanted to clarify what I'm saying in this last part about the process working is the negligible risk recommendations of the National Academy of Sciences in regard to the fungicides. They have taken the Captan decision. There are 44 crops that are cancelled, and it's more than just quinces. EPA has not gone the next step of reducing the tolerances. That's the last step in the process.

I wish you had asked Dr. Moore his intentions on that because, talking with him, that is going to be done. That is the last step. That will be a step that will have to be taken in the EBDC situation.

They went straight at what the National Academy suggested they do, and they're doing it. Two of the materials on there aren't even used anymore. They're not even registered on food crops anymore.

We're attacking that fungicide problem. Is it perfect? No. If we went on to say that we agreed with the agency that we've got to perhaps get some legislative fixes in this whole situation, to smooth this whole thing out so that Food, Drug and Cosmetic and FIFRA are not working at odds with one another; otherwise, we're always going to be debating these things and being at cross purposes.

Senator LIEBERMAN. Let me suggest to you that one of the things that I feel, as I listen to this, is really impatience. Whatever changes are made ought to create a system that will not allow a chemical like Alar to be used for 19 years before we protect——

Mr. MCCARTHY. It serves nobody any purpose for issues to linger on. I don't think anybody is, in hindsight, happy about some of the things that have drug out into the seventies and into the eighties. Hopefully, that isn't going to happen again; that we're able to get on top of these things and do them more quickly.

Senator LIEBERMAN. Okay, thank you.

Senator REID. One of the things that keeps coming to me and I don't understand, Ms. Hathaway, you indicated that there should be a cessation of the sale and manufacture of Alar, but the EPA, even if they're wrong, there's nothing that the manufacturer can do. There are no damages. The most they can do is prove that it should go back on the market. So the only ones benefitting from the non-termination order is the manufacturer of the Alar. Right?

Ms. HATHAWAY. I agree with that, and, in fact, there are a lot of people harmed by the continued sale of the chemical. Apple growers whom I have met with—many of them are angry at the Natural Resources Defense Council for talking out of school, so to speak, for telling the public what many people on Capitol Hill, what many people in the agency, what many people in the environmental community knew, which was that Alar was a very dangerous chemical—they, nevertheless, are very angry also that this chemical is still in the food supply and that it's still legal to use, and that some growers out there are going to persist in using it.

Senator REID. One other thing—and this was brought up with the first panel this morning: if we see in a grocery store a sign that says, "This product has no pesticide on it," what's to prevent the store owner from printing that sign and sticking it on the produce? There's no way to substantiate that what they're saying is true. In fact, it's my understanding that some of the testing that's been done, and that's been indicated from some of the testimony this morning, is that they put the sign there with no backup whatsoever. Is that right?

Ms. HATHAWAY. Apparently, yes. There are people who represent their fruits are Alar-free that, in fact, were treated with Alar. When CBS estimated that 32 percent of the apples, of the total apples, were treated with Alar in this year, they found that a similar percentage of apples which were claimed to be daminozide-free also had daminozide. So it didn't even seem to matter, not even a little, whether there was a sign up that said "Alar-free" or no sign up.

I think that that is indicative of the fact that, until this chemical is just illegal, people are not going to feel confident that when they're told something is safe and has no Alar, it, indeed, will be safe.

I think part of the problem is it is extremely expensive to test for Alar. I can't fault growers for not wanting to use a very sophisticated test to look for Alar. It is the Government's responsibility. The test that's required to find the breakdown product UDMH was only used three times in the last fiscal year by the Food and Drug Administration. That's because it's expensive. It's time-consuming, and they feel like they should be using their resources elsewhere.

It's not the growers' fault, but if the chemical is dangerous and if people are going to need assurances that they are getting food

that's free of this chemical, the only way to do that is to ban the chemical.

Senator REID. One last question: the organization by which you're employed, how is it financed?

Ms. HATHAWAY. It gets about half of the resources from foundation grants, from various different foundations, and the rest from individual contributors. We have about 100,000 members who are contributors to our organization.

Senator REID. I appreciate everyone's testimony here this day. You've been patient. I think it gives the committee and its staff a lot of work to do. Thank you very much.

This subcommittee stands in recess pending call of the Chair.

[Whereupon, at 3:28 p.m., the subcommittee recessed, to reconvene at the call of the Chair.]

[Statements and responses to additional questions submitted for the record follow:]

TESTIMONY OF RALPH NADER

BEFORE THE SUBCOMMITTEE ON TOXIC SUBSTANCES, ENVIRONMENTAL OVERSIGHT, RESEARCH AND DEVELOPMENT

UNITED STATES SENATE

MAY 15, 1989

Mr. Chairman and distinguished members of the Committee, I want to thank you for inviting me to testify today on the critical issue of pesticides and the widespread health threats posed by the chemicals Rachel Carson referred to as "elixirs of death."

In spite of congressional action on a wide range of laws to protect public health and the environment over the last 20 years, today virtually every American is exposed in some way to the use of approximately 2.6 billion pounds of pesticides a year. Unlike most other toxic chemicals, pesticides, are legally dispersed in the environment and on our food.

One of the most repugnant aspects of this problem was best amplified recently by a study done by the Natural Resources Defense Council (NRDC), "Intolerable Risk: Pesticides in our Children's Food." The NRDC report brought much needed attention to the additional risks pesticides pose to children. Infants and small children are proportionately exposed to much higher doses of pesticides, relative to their body weight and food consumption patterns than adults. In an infant's first year of life his or her meals may legally contain hundreds of different pesticides, many of which are carcinogens. Even if children breast feed, studies done for the Environmental Protection Agency (EPA) have shown that most children will be exposed to several toxic chemicals in mother's milk, including the persistent DDT metabolite known as DDE -- 17 years after DDT was banned for most uses! The children of farmers and farmworkers face additional food and non-food exposures (and risks) to pesticides in their air and water.

While it is not likely that every American's daily diet will contain all of the 300 or more pesticides used on food, it is likely that many will be present on most foods and others have even be found in our water. It is just as frightening that our laws and government allow for such a menu of poison. Many of the older pesticides, still widely used, would probably not be allowed to enter the market if they were developed today. However, they remain on the market through loopholes in public health protection statutes created for them by Congress.

Today Americans have at least a one in four chance of contracting cancer and a one in five chance of dying from cancer, according to the Department of Health and Human Services (DHHS). The American Cancer Society estimates that one million new cases of cancer will be diagnosed this year. Yet we endure additional cancer risks from pesticides that begin with an infant's first meal. There should be zero tolerance of policies that risk additional cancers given the largely environmentally induced epidemic we are already experiencing. -- According to a DHHS report, "most scientists now consider that about one third to two thirds of all cancers are associated with the environment in which we live and work."

However, based on the EPA's announced policy of October 19, 1988, the Agency would like to proceed with a policy of "acceptable" risk in regulating pesticides. The implications for continuing a policy that allows cancer causing pesticides in food are major. It means we will continue to see decisions such as the Alar (daminozide) and captan fiascoes which unnecessarily extend the use of carcinogens in the food supply and the environment. -- A recent study by the U.S. Public Interest Research Group (U.S. PIRG) found that at least 60 pesticides which the EPA believes may be carcinogenic are allowed on commonly eaten foods. The study reported that many of these foods, such as apples, beef, corn, tomatoes, peaches and milk, may legally contain 20 or more of these pesticides. Only 11 of these 60 pesticides are in EPA's Special Review process. The Agency seems determined to continue the use of most of these pesticides based on misleading or incomplete information from food and chemical companies.

Until the EPA can prove risk assessment to be more of an exact science than it is today, it should move to ban the sale and use of carcinogens immediately. These chemicals pose more than a risk to the food supply, they endanger people all along the stream of commerce, from production to application. It is unacceptable for the government to defend the use of a cancer causing agent given the paucity of scientific knowledge about that chemical's use, other chronic health effects, the formula's other ingredients, synergism with other companion pesticides and fertilizers and greater threat to sensitive groups such as infants and children.

All too often, the EPA gerrymanders its decisions about such matters by claiming (with no credibility) to have accurate dietary or pesticide use information that "reduces" the risks posed by a chemical. After nine years in Special Review, the EPA this year finally acted on captan. They banned its use on some foods but continued it on high volume foods such as grapes because of its "$1.2 million a year benefits" to the grape and wine industries.

The message is clear, we can no longer wait for agencies such as the EPA and the Food and Drug Administration (FDA) to protect public health and the environment from pesticides. Their recent statements that "the food supply is safe" after failing to suspend the use of Alar (daminozide) and captan on apples and other foods were the latest examples of a policy that pits human health and the environment against corporate profit statements.

Although Congress reauthorized the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) last year, the new law was accurately dubbed "FIFRA Light" in the media because it was so weak. The main improvements made in FIFRA include a 10 year time table to complete the retesting of approximately 600 active pesticide ingredients and the partial repeal of the indemnification and disposal obligations previously borne by the federal government. With the exception of the testing time table, the new law will not address many of the problems posed by pesticides today. For example,

even the new retesting deadlines fail to mandate comprehensive health testing for neurotoxic effects.

We must therefore act as consumers, as legislators and responsible food and agricultural producers to curb the use of these chemicals today if we are to avoid the "silent spring" that Rachel Carson so ominously predicted 27 years ago. It is time to realize that pesticides are the silent violence of chemicals and that we need a national policy to phase out their use and embrace non-polluting sustainable agricultural techniques.

FOOD SAFETY

While considerable attention has recently been paid to pesticides in food by the media, the focus has mainly been on Alar and its metabolite unsymmetrical dimethylhydrazine (UDMH) in apples. However, the problem is much broader than one carcinogen on one crop. In EPA's October 1988 policy statement on pesticides in food, the Agency said "there is at least 'limited evidence' of carcinogenicity (virtually all from animal studies) for 66 or more of the approximately 360 food-use pesticides already approved for use...EPA expects this number to become somewhat larger as it receives and evaluates more studies on the food-use pesticides."

In February of 1987, the EPA ranked pesticide exposures in food as its third most serious environmental health threat -- estimating a risk of 6,000 additional cancers per year. In May of 1987, the National Academy of Sciences (NAS) released a report analyzing the increased cancer risks posed by the use of pesticides on food. The NAS reported that, by volume, 90 percent of all fungicides, 60 percent of all herbicides and 30 percent of all insecticides may cause cancer. The report also reiterated that the EPA had only invoked the Delaney Clause of the Food Drug and Cosmetic Act (FDCA) three times to prohibit a pesticide from being used on a food commodity, (fosetyl al on hops, amitraz and permethrin on apples).

Many of the more hazardous pesticides are used on a wide variety of crops. For example, approximately one third of all vegetables and fruits, including apples, grown in the U.S. are treated with a group of fungicides known as ethylene bisdithiocarbamates (EBDCs). -- (Almost 35 times more widely used than Alar.) The EBDC fungicides include mancozeb, maneb, metiram and zineb. Through food processing, cooking, storage and digestion, EBDCs break down and concentrate into a carcinogenic metabolite known as ethylenethiourea (ETU). The EPA says that the "entire U.S. population is potentially subject to dietary exposure to ETU." After over 11 years in EPA's Special Review process, the Agency is expected to announce a decision to curtail some food uses of EBDCs but, predictably will not immediately suspend all uses.

In the case of Alar, Uniroyal has chosen to keep its product on the market 16 years after its metabolite (UDMH) was first found to be carcinogenic by the U.S. Air Force and now insists that it is "only" used on 5 percent of the apple crop. However, the public has no way of knowing which apples are tainted, causing people to avoid all apples. If Uniroyal had acted responsibly and voluntarily pulled their product off the market years ago, the apple industry would not have faced such sudden losses. This was echoed last week as the Processed Apple Institute also urged the EPA to ban Alar due to slumping sales and consumer outcry. The manufacturers of EBDCs, DuPont, FMC and Rohm & Haas now have an opportunity to spare the growers, food stores and the public a similar ordeal. (DuPont already claims to be voluntarily phasing out CFCs in response to ozone depletion.) After all, chemical companies have enjoyed 20 to 30 years worth of profits from EBDC fungicides. They can well afford to give them up if they choose.

Clearly the resources of the EPA are wholly inadequate given EPA's enormous task of setting food safety limits (tolerances) on more than 8,000 food items for 300 to 400 ingredients in over 40,000 pesticide formulas. Similarly, allocations at the FDA to carry out its responsibility for monitoring and enforcement are as bad or worse. The combined pesticide program budgets ($40 million at EPA and $14 million at FDA) total less than two hours of spending at the Pentagon. Certainly the registration fees added to FIFRA last year need to be enhanced along with new monitoring fees to allow the FDA and the U.S. Department of Agriculture (USDA) to improve both their technological and personnel resources for monitoring and enforcement duties.

Along with greater resources, the agencies need to interpret the laws correctly or ask for the enactment of stronger laws. Currently, FIFRA and the FDCA are regarded within the regulated community as "industry friendly" statutes. Pesticides are automatically assumed to have benefits which the EPA usually interprets to out-weigh health risks. Dr. John Moore at the EPA was quoted on CBS's "Sixty Minutes" as saying that the law does not allow him to quickly remove pesticides such as Alar from the market. By opting only for "cancellation" rather than "suspension", the EPA will allow Alar to remain on the market for another 18 months, or longer, while lenghty cancellation proceedures against Uniroyal begin. However, this is not necessary, the EPA does have the power to suspend Alar effective this week if they agree that it represents an "imminent hazard."

While the <u>EPA agrees that Alar residues on apples do represent unreasonable risks</u>, which exceed one cancer in a million, <u>the Agency chooses not to consider a cancer risk to children to be an "imminent hazard</u>." The EPA estimates that Alar puts 9 children in a million at risk over the next 18 months. A recent Congressional Research Service (CRS) report commented that the difference of opinion between NRDC and the EPA on pesticides in food is more "an indication of the difficulty of conducting risk assessments, as well as a reflection of legitimate scientific disagreements."

Balancing health risks against economic benefits further clouds any effort to assess risks. Because Alar's "benefits" are largely cosmetic, the moral unacceptability of risk-benefit analysis is self evident. However, because Alar's metabolite UDMH may be present in elevated levels in processed food, the EPA could invoke the risk only provision of the FDCA (the Delaney Clause) which gives the Agency authority to revoke or disallow a food tolerance for any carcinogen whose residues concentrate in processed food.

The 1987 NAS report summarized other exceptions that the EPA has made to the risk only Delaney Clause. The insecticide permethrin, a possible carcinogen, concentrates 230-fold in processed tomatoes. Instead of banning its use on all tomatoes the EPA restricted its tomato uses to "Tomatoes Grown in Florida for Final Marketing as Fresh Tomatoes." Given the status of monitoring by the FDA, this policy presents some serious enforcement questions. -- No wonder the Grocery Manufacturers of America (GMA) are pushing legislation to allow the EPA to preempt the right of states like California from setting more stringent food safety standards. They know that the EPA will not ban something until all hell breaks loose, as it did when a few states decided to crack down on ethylene dibromide (EDB) in 1984. Unfortunately, the GMA has forgotten that a safe food supply is in their interest, mediocre regulation is not.

Recently some local food chains led by Raley's of California, have broken away from this mentality and are having their food tested by private labs. -- In some cases these labs are doing a better job than the FDA. While this practice can be abused by unscrupulous retailers, those in the industry who are sincerely competing to sell organic foods or foods with fewer pesticide residues are at least headed in the right direction. The next step that the food industry can take is to establish organic food sections in their produce departments. Growth in this area could be one of the best ways American farmers could compete with foreign imports. Some chains have already required contracts from growers that stipulate no use of pesticides in Special Review. With only 11 of 60 or more possible carcinogens in Special Review, this is not as bold a step as it seems.

INADEQUATE REGULATION & CONTROL

Even with relatively small amounts of knowledge about the possible risks posed by pesticides, what we do know should call into question the level of use they now enjoy. It is irresponsible to prescribe the continued use of these poisons when so many factors are not fully taken into account by the EPA and FDA as they "regulate" pesticides for both food and non-food uses. The following are some of the well documented short-comings of our current national pesticide policy:

*** The EPA fails to govern its regulation of pesticides by the higher risks posed to sensitive subpopulations such as infants, children and pregnant women. The Agency also fails to

calculate total dietary exposures from all foods and all pesticides. They also use out-moded dietary data for different populations even when estimating individual pesticide exposure. The Agency still uses food consumption information collected in the 1960s which assumes that average adults consume no more than 7.5 ounces per year of melon, eggplant, avocados and other foods. The NRDC estimated that children eat six times more apples than the EPA assumes. This example illustrates the absolute absurdity of EPA's tolerance levels for food because millions of Americans today eat far larger amounts of these foods. Congress should pay particular attention to this major weakness in EPA's underlying assumptions. Even the Agency's most recent dietary survey data used in its Tolerance Assessment System (TAS) is more than ten years old. Congress should demand to know how the Agency can regulate with such poor data and why more current data is not a basic requirement in their calculations.

*** An October 1986 report (RCED-87-7) by the General Accounting Office (GAO) revealed that the FDA is not adequately monitoring pesticides residues in food. The GAO found that the FDA's pesticide monitoring cannot detect 60 percent of the pesticide likely to appear on food. It further found that the undetected pesticides are often among the most dangerous ones. Some of these include Alar, EBDCs, and their metabolites UDMH & ETU, for which the FDA tested only 125 and 76 separate samples respectively between 1979 and 1985. The FDA's tests also do not detect alachlor, the most widely used herbicide in the U.S.

The GAO also found that the FDA was monitoring less than one percent of domestic food and only slightly more of imported food. Even when the FDA found violations, it failed to invoke sanctions against violators. The GAO found that the FDA also lacked resources to do an adequate job of monitoring. For example, the FDA only allocated $13.7 million for monitoring pesticides on all domestic and imported food in 1985.

*** Another study by the GAO released on May 3 of this year reported that the EPA program to monitor the export of banned or unregistered pesticides, estimated at about 100 million pounds a year is nonexistent. "EPA received notices on only about 26 percent of the exported products" according to the GAO. This means that the countries from whom we receive as much as 25 percent of our fresh fruit and vegetables may not be getting proper warning and use information about the hazards of these banned and unregistered pesticides.

*** Only 9 states require comprehensive data on the use of an estimated 1.6 billion pounds of pesticides on crops each year in the U.S. The states are: California, Connecticut, Kansas, Maine, Massachusetts, New Hampshire, New Jersey, New York and Texas. If the FDA had better information on pesticide use in the other 31 states, they would know better what they were monitoring for and it would be

much less expensive to do so. More accurate use information would also help the EPA to more accurately consider exposure as well.

*** While approximately 400 out of 600 pesticide active ingredients are allowed on food, only 195 have been issued new "registration standards" by the EPA (even this does not mean that they have been fully tested). EPA officials have also been hinting that they may not meet the new FIFRA reregistration time tables. And none of the 1,200 so-called inert ingredients used on any of more then 40,000 pesticide formulations are required by statute to be tested or regulated based on their health effects. The EPA began requesting test data on 110 inerts in 1987 but the Agency does not consider the added risks posed by these companion chemicals when regulating an active ingredient. Many, such as asbestos fibers, benzene, chloroform, formaldehyde and methylene chloride are known carcinogens.

*** The EPA also fails to calculate the added risk of exposure to other pesticide active ingredients that are likely to be on the same foods. For example, Alar is weighed by the EPA separately from the Agency's regulation of captan which is also used on apples. -- While the EPA considered other fungicidal risks and alternatives to captan it did not consider risks posed by other pesticides allowed on the same food such as Alar (a cosmetic growth regulator) or lead arsenate (an insecticide).

In this regard the Agency also fails to calculate or require data on the cumulative or synergistic effects of exposure to food-use pesticides and fertilizers likely to be used and found together. This is now done, to some extent, with pharmaceutical products but is not yet part of the EPA's current risk assessments. A well known example of synergistic health effects is the several fold risk of lung cancer to cigarette smokers who are also exposed to asbestos. The level of risk is far greater than the combined risks of smoking and inhaling asbestos fibers.

*** Multiple exposures to pesticides through all foods, drinking water and the air (toxic fog) are not currently factored into the EPA's regulation of pesticides. A June 1987 USDA study reported that the ground water supply of 50 million rural Americans is at risk of contamination from pesticides used in agriculture. The EPA reported in December of 1988 that 77 pesticides have been found in the well water of 39 states. In October the Agency said that it would like to begin considering drinking water exposures when regulating pesticides in food but has yet to do so. And while the EPA suspects that 127 pesticides may leach into ground water, only six active ingredients are currently regulated under the Safe Drinking Water Act, 17 more were proposed by the Agency on May 2.

*** Most pesticide food tolerances were set in the 50s and 60s and reflect a "margin of safety" that errs on the side of the food

grower not the consumer. Too often these tolerance were set high enough to insure that no one was caught violating them, instead of low enough to insure food safety. To now say that actual residues are usually below these tolerances is comparable to saying that few people are violating a 150 mile per hour speed limit. A March CRS report said "Current detection technology can routinely indicate residues in the parts per trillion...Most of the tolerances for these pesticides were presumably first granted when the state of the art detection method could only identify the pesticide in the part per million range."

*** The EPA is only sporadically requiring testing on neurotoxic health effects of pesticides. They especially lack requirements for neurotoxic behavioral effects as a routine test for each chemical. Another area of concern with little activity at EPA is the effects of pesticides on the body's immune system.

*** Some pesticides such as heptachlor, toxaphene and silvex are no longer legally used on food but their residues are still allowed until they work their way out of the food chain. However, because a pesticide is no longer legally used on food does not mean that illegal use is also not a problem. There have been several well publicized incidents of illegal use of pesticides. In March of this year heptachlor tainted feed forced the destruction of four hundred thousand chickens in Arkansas and in 1985 aldicarb was found to have been illegally used on watermelons and cucumbers in California and the northwest. Only now is the Agency moving to further restrict the sale of heptachlor. However, illegal use is not restricted to this country. Another GAO report (RCED 86-219) released in September of 1986 also found poor monitoring and enforcement buy the FDA of illegal pesticide residues on imported food.

Because there is no known safe level of exposure to carcinogens, the EPA in the past has attempted to establish theoretic "de minimis" or "negligible" risk exposure levels that are used to justify permissible levels of cancer causing pesticides in food and water. Having never fully factored in the missing risk variables mentioned above it is easy to see why there is so little consensus on the pseudo-science of risk assessment as it is currently practiced at the EPA and the FDA.

GROUND WATER

Nearly half of the U.S. population relies on ground water for drinking. This includes virtually all of the rural population of the U.S. A June USDA report estimated that 767 counties in spanning every region have a combination of vulnerable ground water and moderate to high pesticide use.

Based on over 100 studies, the EPA in December issued a report

on pesticides in well water. Of the 77 pesticides they said were found in the well water of 39 states, 33 were carcinogens. The report represented sampling from approximately 45,000 of the nation's 13 million wells. Pesticides were found in 11,000 wells and over 5,000 well samples exceeded health advisory levels. The EPA is in the process of conducting a one time survey of pesticides in ground water. They are testing wells for 127 suspected leaching pesticides.

In Florida, more than a thousand wells were condemned because of contamination from EDB. In Iowa, officials estimate that more than 25 percent of the population using public water supplies receives water containing pesticides. A survey done last year by the state of Minnesota found pesticide contamination in 33 percent of the 500 wells tested in 51 counties.

Dangerous pesticides such as aldicarb, alachlor and atrazine have now been found in every region. Little if any national monitoring is being done. For the most part, the EPA relies on the states for the information. Some data is generated by pesticide registrants but much more is needed.

Current EPA policy is based on EPA's "Agricultural Chemicals in Ground Water Strategy" announced last February. This proposal has been roundly criticized by environmental groups for relying too heavily upon states to regulate; for allowing certain areas of ground water to be written off as pollution sinks; for using cost based clean up standards instead of health based standards; and for defining the ground water to be protected too narrowly. Some state governments have called the EPA strategy unworkable.

While many states claim to have ground water protection programs or plans, only a hand full of states, such as Iowa and Minnesota are leading the country in identifying their problem and proposing strong measures such as source controls to prevent contamination. However, EPA's current strategy could hardly be called leadership. Instead it appears to follow rather than lead, in effect following the slowest states.

Last July, your full committee, the Environment and Public Works Committee reported out a ground water safety bill that would have made a number of important improvements had it become law. Unfortunately, the bill would still have allowed carcinogens in drinking water at some levels. It also would have let agri-business off the hook for clean up liability from pesticide contamination of ground water. -- Although I must add that in doing so the Committee had the wisdom to transfer liability to the chemical manufacturer. It also would have given farmers an incentive to keep records of pesticide use and required pesticide manufacturers to pay for more monitoring and the replacement of contaminated water supplies.

The legislative solution to protect ground water from pesticides may best be sought by addressing all ground water pollution sources such as fertilizers and industrial solvents together. Ground water is the last vast unprotected resource that calls out for comprehensive legislation with an emphasis on prevention. Once ground water is contaminated it can take decades if not centuries to be cleaned and as the Superfund program has taught us, it is very costly. Prevention through strict source controls is the only way.

FARMWORKERS

According to the DHHS, there are an estimated 3 million migrant and seasonal farmworkers in the U.S. They are the people who harvest our food and yet they are directly exposed to the highest doses of pesticide poisons most often. Thousands of farmworker children are put at additional risk by their proximity to fields and other exposures, legal and illegal. A study done for the National Cancer Institute found that farmers exposed to herbicides were six times more likely to develop non-Hodgkins lymphoma (a form of cancer) than the general population.

Last June the EPA proposed new farmworker safety practices. Dr. Marion Moses of the United Farm Workers (UFW) called the proposal a "grower protection standard...the regulations are disgraceful, very weak, timid." Not surprisingly, the National Council of Agricultural Employers commended the proposal as "thoughtful...thorough." Even the EPA's Science Advisory Panel criticized the plan saying it "does not go far enough in protecting farmworkers." They noted that California and Texas have already adopted stronger standards and added that the "philosophy of establishing only minimum standards seems inappropriate." Again, lack of resources is an additional problem. The EPA has less than 6 full time staff working on farmworker protection regulations.

Meanwhile, an estimated 300,000 farmworkers suffer from pesticide related illnesses each year. These health effects include acute poisonings but also can include birth defects, learning disabilities, hyperactivity and seizures.

In December of 1987 I joined with many others in supporting the UFW call for a national boycott of California table grapes. One of the main reasons for the boycott and central demands of the union is a ban on five of the most dangerous pesticides used on grapes. These include: captan, parathion, phosdrin, dinoseb and methyl bromide. The boycott can also give the UFW the bargaining power it needs to force greater compliance with health protection provisions of the stronger but unenforced California farm labor laws.

SUGGESTIONS FOR CONSUMERS

The grape boycott is one of the ways consumers can vote with

their shopping carts and send a message to the food industry that pesticides are no longer tolerable on their food. Other useful consumer actions can include supermarket petitions, organizing neighbors to ask store managers to stock organic food and locally grown food in the produce section and encouraging supermarkets to do their own monitoring of produce.

Supermarket chains increasingly recognize the demand for pesticide free food. Consumers should be greatly encouraged to approach store managers about forming an alliance with them. Indeed supermarket customers can form loosely organized committees to meet and discuss new programs with store managers.

SUGGESTIONS FOR INDUSTRY

Wholesalers and retailers should begin monitoring of produce and demand that chemical companies provide a practical method to identify pesticide residues. Food retailers should refrain from misleading advertising that promises "pesticide free food" unless they can certify their claims. These same companies should ask growers to begin phasing out their pesticide use and adopt low-input sustainable agricultural practices. Large food producing companies can also send these messages to growers and adopt these policies on their own farms. Small family farmers may be in a position to profit from a growing consumer awareness and demand for a safer product. Family farmers can convert to organic and sustainable agriculture more easily than many monoculture factory farm operations.

SUGGESTIONS FOR THE EPA AND CONGRESS

*** Immediately begin a program to ban carcinogens from the market and seize or order the destruction of existing stocks of banned pesticides, such as heptachlor, which are still used or allowed on food.

*** Oppose any attempt by special interest groups to preempt the right of states to regulate pesticides more stringently than the federal government. All other major environmental statutes allow for the wisdom of the states to lead the way if they choose. -- If a federal statute is really protective of public health, there will be no reason for states to challenge it.

*** The EPA should be required to use the greater risks posed by pesticides to sensitive population groups, such as infants and children, to govern it regulation of pesticides.

*** The EPA should be required to use accurate up to date dietary information when calculating exposures.

*** The EPA should calculate the added risk of exposure to pesticide inerts, metabolites, other likely used pesticides and fertilizers and their cumulative or synergistic health effects when assessing the risks of pesticide exposure.

*** The EPA should calculate the full dietary exposure of pesticides through the diet as well as other routes of exposure such as drinking water, air, farmworker exposure, garden, home exposure etc. in determining the full body burden of pesticides and their full health risks to individuals and the population as a whole.

*** Manufacturers of pesticides should not be allowed to continue their registration or food tolerance unless they have provided the EPA and FDA with practical methods of monitoring for their pesticides.

*** Pesticides that have been banned for use on food should have their tolerances revoked. Heptachlor is a good example of where the EPA has failed to do this in a timely fashion.

*** The EPA should require pesticide manufacturers to test for more health effects, such as neurotoxic behavioral effects, with special attention given to the potential for learning disabilities and other effects on children.

*** Pesticide should not be used unless the user or applicator is willing to supply federal and/or local government with accurate records of its use.

*** The resources of the FDA should be significantly increased to carry out adequate monitoring and enforcement of pesticide residues on domestic and imported food.

*** Congress should ban the export of banned and unregistered pesticides and insure that users of registered pesticides in receiving countries are adequately notified of the hazards of all pesticides shipped to them from the U.S.

*** The USDA should encourage more demonstration projects, research and grants to promote more widespread application of low-input farming techniques.

*** The EPA and FDA currently have inadequately used their authority to notify consumers about pesticides used on their food. Currently, retailers are supposed to notify consumers about any waxes used on produce and retailers themselves are given labels on crates informing them of post-harvest pesticide applications. And recently the EPA proposed posting signs in retail stores regarding sulfites used on grapes. But there has not been a serious effort to notify consumers of the many pesticides applied to their food.

Those engaged in deprecating the seriousness of risks posed by agricultural chemicals and other pesticides to consumers, workers and especially infants may wish to consider the following: If regulation and other internal corporate systems are not strengthened to test, monitor and control the vast array of toxic chemicals now in use, the future will see the emergence of even more reckless efforts to market more virulent chemicals in the rabid quest for market share.

Thank you again for your attention to this important matter.

Testimony of S. Mason Carbaugh

Commissioner of Agriculture and Consumer Services

Presented on May 15, 1989 to

The Congressional Subcommittee on Toxic Substances,

Environmental Oversight, Research and Development

Senator Reid and Members of the Subcommittee, I am S. Mason Carbaugh, Commissioner of Agriculture for the Virginia Department of Agriculture and Consumer Services. I appreciate the opportunity to appear before you today.

We have seen many changes in agricultural production practices. We have gone from a labor intensive to a mechanical system which allows the American farmer to produce sufficient quantities of food to feed his family and over seventy others. This has also been accomplished through the use of pesticides and fertilizers.

While recent public opinion and attitudes with respect to current farm management techniques might give rise to food safety concerns, it is my belief that American consumers have access to the safest, most wholesome and diverse food supply at a lower cost per capita than any other consumers in the world.

Virginia's original Pesticide Law was passed in 1948. Until Congress passed FIFRA in the early 1970's the focus of our program was on product. Purchasers were assured through our sampling and testing programs that pesticides would perform as advertised and that formulation matched label description.

When FIFRA was amended the focus shifted to proper use of pesticides. Virginia's Law was amended to track federal legislation in 1975. When our law was amended, we began issuing licenses and certificates to private and commercial applicators and entering into cooperative agreements with EPA to ensure the safe and proper use of pesticides.

While Virginia has had a long history of involvement in pesticide management programs, several recent events required us to examine our role to see if improvements to our pesticide management statutes were needed.

Citizens have long been concerned about commercial applicators who have defrauded them by providing unnecessary services. Citizens have also become increasingly aware of residues in our food supply. But perhaps the single event which prompted our review was the unfortunate death of two of our citizens which resulted from an improper application by a commercial applicator.

As a result of these events, a study was undertaken in July, 1988 to determine what changes were needed to Virginia's laws to allow us to more effectively manage our pesticide programs. The study was originally designed to last 12 months.

However, Governor Baliles asked that we complete our work prior to the 1989 session of the General Assembly. The final report was presented to the Governor on December 21, 1988.

Key recommendations contained in the study addressed the following areas:

Program Administration and Funding:

Management of pesticides should be based on a sound policy which balances the need for pesticide use and economic opportunity with the responsibility of the Commonwealth to protect public health and environmental quality. A new Pesticide Control Board was recommended to be responsible for the development of policies, regulations and oversight of program implementation. The program should be adequately staffed to carry out new and existing policies.

Registration:

Virginia should establish a special review procedure for pesticides proposed for registration or already registered in Virginia if it is determined that a product poses a potential risk to Virginia's environment or citizens.

Licensing of Businesses:

The report recommended that all businesses that sell, distribute, store or apply pesticides be licensed according to criteria established by the new Board.

Training and Certification of Techniciens:

Anyone who applies or recommends the use of any pesticide commercially should be properly trained, certified and identified in one of two new commercial certification classes: a certified commercial applicator or a certified commercial technician. The study also recommended that training programs be improved.

Enforcement:

To strengthen and expand enforcement options, a civil penalties section needs to be included in the Law. The Board should have the authority to investigate and prosecute cases of fraud.

Other recommendations addressed the following: Disposal; Bulk Storage; Worker and Public Safety; Environmental Protection; Public Information and Education; Monitoring and Analysis and Research.

As a result of these recommendations, H.B. 1881, the Virginia Pesticide Control Act was introduced and passed by the 1989 Session of the General Assembly. Our new law passed both Houses without a dissenting vote. This indicated a commitment by all to be responsive to pesticide management issues in Virginia.

All the Study recommendations are addressed in the new legislation specifically or in the regulations the Board will adopt. Major provisions in the new law are:

1) An 11 member Pesticide Control Board will be appointed by the Governor to provide oversight for the management of pesticides in Virginia. The Board has been granted broad authority to promulgate regulations in the following areas: License businesses that manufacture, store, sell, mix, recommend for use or apply pesticides, registration of pesticides; requiring reporting and record keeping; establishing training and testing standards for commercial applicators, registered technicians and private applicators; revoking suspending or denying licenses or certificates requiring licenses and certificate holders to inform the public when using pesticides in and around structures; establish a fee structure to defray costs; classifying or subclassifying certifications or certificates and such other regulations as necessary and convenient.

2) An annual business license will be required for all commercial firms who sell and/or apply pesticides in Virginia. This will be done so that we will be able to more closely monitor pesticide use, purchases, distribution and storage.

3) Previously, commercial applicators were only licensed if they applied restricted use pesticides. The new Law requires commercial applicators to be certified when applying either general or restricted use pesticides.

4) A two-tiered system of certification will be developed for commercial applicators. A commercial for hire applicator will be required to be certified. In addition, an individual with less experience may qualify as a registered technician. A registered technician must be under the supervision of a certified applicator when applying restricted use pesticides.

5) A civil penalties section was added which will allow the State a broader range of enforcement options. Civil penalties range from a minimum of $1,000 to a maximum of $100,000 depending on the severity of the violation. In addition, any person, who knowingly violates the provisions of the Act or regulations may be guilty of a Class I Misdemeanor and subject to an additional fine up to $500,000.

6) The evidence of financial responsibility section has been strengthened. Previously a maximum of $200,000 surety bond or liability insurance was authorized. The new Pesticide Control Act establishes a minimum of $200,000 bond or liability insurance policy before a business license will be issued.

To implement Virginia's new and expanded pesticide management program, Governor Baliles recommended and the General Assembly approved a appropriation for FY 89-90 of $787,992.

It is my belief that once all the provisions of the Act are fully implemented, all the findings and recommendations contained in the Study will be operational. Further, once implemented, Virginia will have one of the strongest pesticide management programs in the country.

The Virginia Department of Agriculture and Consumer Services has enjoyed a good working relationship with EPA. We believe, however, that the working relationship between EPA headquarters and the States needs to be strengthened through such organization as the National Association of State Departments of Agriculture. This will provide the opportunity for early state input and review into programs under development. Examples include: groundwater protection, endangered species and worker safety. States and EPA must also become fuller partners to develop new or expanded programs which will provide a balance between environmental protection and economic realities.

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Another role states and the federal government could share is to communicate more clearly the process of risk assessment and management to the public and industry. The need for informed citizens is greater today than at any time in our history. A renewed effort should be undertaken to be sure that information, particularly with respect to food safety, is presented based on the best scientific research information available.

A recent example is the publicity with respect to Alar. Our Division of Dairy and Foods recently sampled 125 lots of fresh apples and apple products. Included in the total were 8 samples from the school lunch program. No detectable levels of Alar were found in any of the school lunch samples. Ninety-one percent of the remaining samples were Alar free. Positive samples showed trace amounts ranging from 1.0 ppm - 2.8 ppm. These results represent to me that the U.S. food supply continues to be one of the safest in the world.

In summary let me say that the study of pesticide management in Virginia provided the framework for significant change.
The continuing challenge we face however is achieving a balanced approach while we minimize the risk to humans and the environment.

The task cannot be accomplished by one individual, group or government. It must be done in a cooperative fashion and I believe that Virginia's farmers, citizens and government are willing to work together.

I have provided a copy of the new Virginia Pesticide Control Act and the Council on the Environment report to your staff.

At this time, I would be happy to answer any question your or the other members of the Committee might have.

1989 SESSION

VIRGINIA ACTS OF ASSEMBLY - CHAPTER

An Act to amend and reenact §§ 2.1-1.6, 2.1-20.4 and 9-6.25:2 of the Code of Virginia, to amend the Code of Virginia by adding in Title 3.1 a chapter numbered 14.1, consisting of Articles 1 through 5, containing sections numbered 3.1-249.27 through 3.1-249.78, and to repeal Chapter 14 of Title 3.1, consisting of Articles 1 through 5, containing §§ 3.1-189 through 3.1-249.26, of the Code of Virginia, relating to the Virginia Pesticide Control Act; penalties.

[H 1881]

Approved

Be it enacted by the General Assembly of Virginia:

1. That §§ 2.1-1.6, 2.1-20.4 and 9-6.25:2 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding in Title 3.1 a chapter numbered 14.1, consisting of Articles 1 through 5, containing sections numbered 3.1-249.27 through 3.1-249.78, as follows:

* * * * * * * * * * *

CHAPTER 14.1.
VIRGINIA PESTICIDE CONTROL ACT.
Article 1.
General Provisions.

§ 3.1-249.27. Definitions.--As used in this chapter, unless the context requires a different meaning:

"Active ingredient" means, in the case of a pesticide other than a plant regulator, defoliant, desiccant, or anti-desiccant, an ingredient which will prevent, destroy, repel or mitigate insects, fungi, rodents, weeds, or other pests .

"Agricultural commodity" means any plant or part thereof, or animal, or animal product, produced by a person, including farmers, ranchers, vineyardists, plant propagators, Christmas tree growers, aquaculturists, floriculturists, orchardists, foresters, nurserymen, wood treaters not for hire, or other comparable persons, primarily for sale, consumption, propagation, or other use by man or animals.

"Board" means the Pesticide Control Board.

"Bond" means a written instrument issued or executed by a bonding, surety, or insurance company licensed to do business in the Commonwealth, or otherwise approved by the Board, guaranteeing the fulfillment of the agreement between the licensee and the customer.

"Certificate" means the document issued to a certified applicator or registered technician who has completed all the requirements of Article 3 (§ 3.1-249.51 et seq.) of this chapter.

"Certification" or "certified" means the recognition granted by the Pesticide Control Board to an applicator upon satisfactory completion of Board approved requirements.

"Commercial applicator" means any applicator who has completed the requirements as determined by the Board, including appropriate training and time in service, to apply for a certification, and who uses or supervises the use of any pesticide for any purpose or on any property other than as provided in the definition of private applicator.

"Commissioner" means the Commissioner of Agriculture and Consumer Services.

"Committee" or "advisory committee" means any advisory committee appointed pursuant to § 3.1-249.29.

"Defoliant" means any substance or mixture of substances intended for causing the leaves or foliage to drop from a plant, with or without causing abscission.

"Department" means the Department of Agriculture and Consumer Services.

"Desiccant" means any substance or mixture of substances intended for artificially accelerating the drying of plant tissue.

"Device" means any instrument or contrivance intended for trapping, destroying, repelling, or mitigating insects or rodents or destroying, repelling, or mitigating fungi, bacteria, or weeds, or such other pests as may be designated by the Commissioner, but not including treated wood products or simple, mechanical devices such as rattraps, or equipment used for the application of pesticide when sold separately therefrom.

"Fumigant" or "fumigation" means any substance which by itself or in combination with any other substance emits or liberates a gas or gases, fumes or vapors, which gas or gases, fumes or vapors, when liberated and used, will destroy vermin, rodents, insects, and other pests, and are usually lethal, poisonous, noxious, or dangerous to human life.

"Fungicide" means any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any fungi or plant disease.

"Herbicide" means any substance or mixture of substances intended for preventing, destroying, repelling or mitigating any weed.

"Ingredient statement" or "guaranteed analysis statement" means a statement of the name and percentage of each active ingredient, together with the total percentage of the inert ingredients, in the pesticide; and, in addition, in case the pesticide contains arsenic in any form, a statement of the percentages of total and water soluble arsenic.

"Insect" means any of the numerous small invertebrate animals generally having a body more or less obviously segmented, for the most part belonging to the class Insecta, comprising six-legged, usually winged forms, as, for example, beetles, bugs, bees, flies, and to other allied classes of arthropods whose members are wingless and usually have more than six legs, as, for example, spiders, mites, ticks, centipedes, and wood lice, also nematodes and other worms, or any other invertebrates which are destructive, constitute a liability, and may be classed as pests.

"Insecticide" means any substance or mixture of substances intended for preventing, destroying, repelling or mitigating any insects which may be present in any environment whatsoever.

"Label" means the written, printed or graphic matter on, or attached to, the pesticide or device, or the immediate container thereof, and the outside container or wrapper of the retail package, if any, of the pesticide or device.

"Labeling" means all labels and other written, printed, or graphic matter (i) upon the pesticide or device or any of its containers or wrappers, (ii) accompanying the pesticide or device at any time, or (iii) to which reference is made on the label or in literature accompanying the pesticide or device, except when accurate, nonmisleading reference is made to current official publications of the agricultural experiment station, the Virginia Polytechnic Institute and State University, the Department of Agriculture and Consumer Services, the State Board of Health, or similar federal institutions or other official agencies of the Commonwealth or other states when such agencies are authorized by law to conduct research in the field of pesticides.

"Licensed" or "licensee" means those businesses which, upon meeting the requirements established by the Pesticide Control Board, are issued a license to engage in the sale, storage, distribution, recommend the use, or application of pesticides in Virginia in exchange for compensation.

"Misbranded" shall apply to any pesticide or device:

1. If its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;

2. If it is an imitation of or is offered for sale under the name of another pesticide;

3. If its labeling bears any reference to registration under this chapter;

4. If the labeling accompanying it does not contain directions for use which are necessary and, if complied with, adequate for the protection of the public;

5. If the label does not contain a warning or caution statement which may be necessary and, if complied with, adequate to prevent injury to living man and other vertebrate animals, vegetation, and useful invertebrate animals;

6. If the label does not bear an ingredient statement or guaranteed analysis statement on that part of the immediate container and on the outside container or wrapper, if there be one, through which the ingredient statement or guaranteed analysis statement on the immediate container cannot be clearly read, of the retail package which is presented or displayed under customary conditions of purchase; provided, that the commissioner may permit the ingredient statement to appear prominently on some other part of the container, if the size or form of the container makes it impracticable to place it on the part of the retail package which is presented or displayed under customary conditions of purchase;

7. If any words, statement, or other information required by or under the authority of this chapter to appear on the labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

8. If in the case of an insecticide, fungicide, or herbicide, when used as directed or in accordance with commonly recognized safe practice, it shall be injurious to living man or other vertebrate animals or vegetation, to which it is applied, or to the person applying such pesticide, excepting pests and weeds; or

9. If in the case of a plant regulator, defoliant, or desiccant when used as directed it shall be injurious to living man or other vertebrate animals, or vegetation to which it is applied, or to the person applying such pesticide; provided, that physical or physiological effects on plants or parts thereof shall not be deemed to be injury, when this is the purpose for which the plant regulator, defoliant, or desiccant was applied, in accordance with the label claims and recommendations.

"Pesticide" means: (i) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any insects, rodents, fungi, bacteria, weeds, or other forms of plant or animal life or viruses, except viruses on or in living man or other animals, which the Commissioner shall declare to be a pest, (ii) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (iii) any substance which is intended to become an active ingredient thereof.

"Pesticide business" means any person engaged in the business of distributing, applying or recommending the use of a product, storing, selling, or offering for sale pesticides for distribution directly to the user. The term "pesticide business" does not include wood treaters not for hire or businesses exempted by regulations adopted by the Board.

"Plant regulator" means any substance or mixture of substances, intended through physiological action, for accelerating or retarding the rate of growth or rate of maturation, or for otherwise altering the behavior of ornamental or crop plants or the produce thereof, but shall not include substances to the extent that they are intended as plant nutrients, trace elements, nutritional chemicals, plant inoculants, and soil amendments.

"Private applicator" means an applicator who uses or supervises the use of any pesticide which is classified for restricted use for purposes of producing any agricultural commodity on property owned or rented by him or his employer or, if applied without compensation other than trading of personal services between producers of agricultural commodities, on the property of another person.

"Registered technician" means an individual who renders services similar to those of a certified commercial applicator, but who has not completed all the training or time in service requirements to be eligible for examination for certification as a commercial applicator and is limited to application of general use pesticides. However, if he applies restricted use pesticides he shall do so only under the direct supervision of a certified commercial applicator.

"Registrant" means the person registering any pesticide pursuant to the provisions of this chapter.

"Repellent" means a substance, not a fumigant, under whatever name known, which may be toxic to insects and related pests, but is generally employed because of its capacity for preventing the entrance or attack of pests.

"Restricted use pesticide" or "pesticide classified for restricted use" means any pesticide classified as restricted by the Administrator of the United States Environmental Protection Agency.

"Rodenticide" means any substance or mixture of substances intended for preventing, destroying, repelling or mitigating rodents or any other vertebrate animal which the Commissioner shall declare to be a pest.

"Serious violation" means a violation of this chapter or regulation promulgated by the Board where there is a substantial probability that death or serious physical harm to persons, serious harm to property, or serious harm to the environment could have resulted from the violation unless the person or licensee did not or could not with the exercise of reasonable diligence know of the violation.

"State special use" or "pesticide classified for restricted use in the Commonwealth" means any pesticide that, after special review, is judged by the Board to be so hazardous or injurious to persons, pollinating insects, animals, crops, wildlife, lands, or the environment, other than the pests it is intended to prevent, destroy, control, or mitigate, that additional restriction on its sale, purpose, use, or possession are required.

"Under the direct supervision of" means the act or process whereby the application of a pesticide is made by a competent person acting under the instructions and control of a certified applicator who is responsible for the actions of that person.

"Unreasonable adverse effects on the environment" means any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.

§ 3.1-249.28. Pesticide Control Board established; appointment of members; terms.—A. There is hereby established a Pesticide Control Board which shall consist of eleven members, to be appointed by the Governor, as follows: two members representing the agricultural or forestal production and related agricultural industries; two members representing the commercial sale or application of pesticides sector, at least one of whom shall be a commercial applicator; two representatives from the public health and environmental community; three citizen members, one of whom the Governor shall appoint as chairman; and the State Forester and the Dean of the College of Agriculture and Life Sciences of Virginia Polytechnic Institute and State University who shall serve as ex officio members of the Board.

B. Terms shall be for four years with initial appointments made on a staggered basis; one member from each of three categories shall receive an initial appointment for two years, one member in each category shall be initially appointed for three years, and the remaining member in each category shall be appointed for a four-year term. Thereafter, all members shall be appointed for terms of four years each. Vacancies occurring, other than by expiration of a term, shall be filled by the Governor in the same manner as the original appointment for the remainder of the unexpired term.

C. The Board shall adopt rules and procedures for the conduct of business.

D. The Board shall meet quarterly and other times upon the call of the chairman.

E. A quorum shall consist of six members.

F. Members shall be reimbursed for reasonable expenses incurred and shall be compensated consistent with § 2.1-20.4.

§ 3.1-249.29. Powers and duties of the Board.—The Board shall have the power and duty to carry out the provisions of this chapter and is authorized to:

1. Appoint such advisory committees as necessary to implement this chapter;

2. Contract for research projects and establish priorities;

3. Publish an annual statistical report and biennial progress report for the Governor and General Assembly;

4. Consult with the Department of Waste Management on the safe and proper disposal of pesticide concentrates, used pesticide containers, and unused pesticides;

5. Consult with the Virginia Department of Labor and Industry on standards and regulations needed to ensure safe working conditions for pest control and agricultural workers;

6. Consult with the Department of Game and Inland Fisheries regarding standards necessary to protect wildlife and fish;

7. Inform the citizens of Virginia as to the desirability and availability of nonchemical and less toxic alternatives to chemical pesticides and the benefits of the safe and proper use of pest control products while promoting the use of integrated pest management techniques and encouraging the development of nonchemical and less toxic alternatives to chemical pesticides;

8. Require that pesticides used in Virginia are adequately tested and are safe for use under local conditions;

9. Require that individuals who sell, store or apply pesticides commercially are adequately trained and observe appropriate safety practices; and

10. Cooperate, receive grants-in-aid, and enter into agreements with any agency of the federal government, of this Commonwealth or political subdivision, or with an agency of another state, in order to promote the purposes of this chapter.

§ 3.1-249.30. Board to adopt regulations.—In addition to the power to promulgate regulations provided for in other sections of this chapter, the Board may promulgate regulations pursuant to the Administrative Process Act (§ 9-6.14.1 et seq.), including but not limited to the following:

1. Licensing of businesses that manufacture, sell, store, recommend for use, mix or apply pesticides.

2. Registration of pesticides for manufacture, distribution, sale, storage, or use in the Commonwealth.

3. Requiring reporting and record keeping related to licensing and registration.

4. Establishing training, testing and standards for certification of commercial applicators, registered technicians, and private applicators.

5. Revoking, suspending or denying licenses (business), registration (products), and certification or certificate (applicators or technicians).

6. Requiring licensees and certificate holders to inform the public when using pesticides in and around structures.

7. Establishing a fee structure for licensure, registration and certification to defray the costs of implementing this chapter.

8. Classifying or subclassifying certification or certificates to be issued under this chapter. Such classifications may include but not be limited to agricultural, forest, ornamental, aquatic, right-of-way or industrial, institutional, structural or health-related pest control.

9. Such other regulations as may be necessary or convenient to carry out the purposes of this chapter.

§ 3.1-249.31. Restriction or prohibition of certain pesticides, pesticide containers and residuals.—The Board is authorized to prescribe regulations to restrict or prohibit the sale or use and disposal of any pesticide or pesticide container or residuals which:

1. Undesirably persists in the environment or increases due to biological amplification or unreasonable adverse effects on the environment;

2. Because of toxicity or inordinate hazard to man, animal,bird or plant may be contrary to the public interest.

§ 3.1-249.32. Complaints to Commissioner or the Board.—Any person may register a written complaint with the Commissioner or the Board relating to the sale, use, storage, handling or disposal of any pesticide and the Commissioner or the Board shall institute an investigation of the alleged damage caused by such pesticide. The Commissioner may seek the advice of other state or federal agencies or institutions. When it is determined that a violation has occurred, the Commissioner shall proceed as provided in § 3.1-249.71 or §

3.1-249.73.

§ 3.1-249.33. Delegation of authority.—The Board may delegate any authority vested in it under this chapter, except the promulgation of regulations, to the Commissioner or other employees of the Department, as the Commissioner may from time to time designate for such purpose.

§ 3.1-249.34. Disposition of fees and penalties collected.—All fees and penalties collected under this chapter shall be paid into a special fund in the state treasury to the credit of the Department to be used in carrying out the provisions of this chapter.

Article 2.

Registration.

§ 3.1-249.35. Registration required.—Every pesticide which is manufactured, distributed, sold, or offered for sale, used or offered for use within the Commonwealth shall be registered in accordance with regulations adopted by the Board.

§ 3.1-249.36. Products registered under Federal Act.—The Commissioner may register and permit the sale and use of any pesticide which has been registered under the provisions of the Federal Insecticide, Fungicide and Rodenticide Act, as amended. Products so registered shall be subject to the registration fees as established by the Board, and to all other provisions of this chapter.

§ 3.1-249.37. Products registered as single pesticide.—Products which have the same formula, and are manufactured by the same person, the labelings of which contain the same claims, and which bear designations identifying the products as the same pesticide, may be registered as a single pesticide without an additional fee.

§ 3.1-249.38. Change in labeling or formulas without reregistration.—Within the discretion of the Commissioner, or his authorized representative, a change in the labeling or formulas of a pesticide may be made within the current period of registration, without requiring a reregistration of the product.

§ 3.1-249.39. Statement to be filed by registrant.—The registrant shall file with the Commissioner, a statement including:

1. The name and address of the registrant and the name and address of the person whose name will appear on the label, if other than the registrant;

2. The name of the pesticide;

3. A complete copy of the labeling accompanying the pesticide and a statement of all claims made and to be made for it including directions for use;

4. If requested, a full description of the tests made and the results thereof upon which the claims are based; and

5. Such other information which may include, but is not limited to, product efficacy, all known health and environmental impacts, and known incidents of human or wildlife illnesses, as determined by the Board.

In the case of renewal of registration, a statement shall be required only with respect to information which is different from that furnished when the pesticide was registered or last reregistered or is in response to additional requirements imposed by the Board.

§ 3.1-249.40. Each brand or grade to be registered; fees.—The registrant, before manufacturing, distributing, selling, offering for sale, or offering for use any pesticide, in the Commonwealth, shall register each brand or grade of such pesticide with the Commissioner annually upon forms furnished by the Department, and shall pay to the Department an annual registration fee for each brand or grade to be offered for sale or use in the Commonwealth. The Commissioner shall issue a registration entitling the registrant to manufacture, distribute or sell all registered brands in the Commonwealth until the expiration of the registration.

§ 3.1-249.41. Submission of complete formula.—The Commissioner, whenever he deems it necessary in the administration of this chapter, may require the submission of the complete formula of any pesticide.

§ 3.1-249.42. When Commissioner to register pesticide.—If it appears to the Commissioner that the composition of the pesticide is such as to warrant the proposed claims for it and if the pesticide and its labeling and other material required to be submitted comply with the requirements of this chapter, the Commissioner shall register the pesticide.

§ 3.1-249.43. When Commissioner to notify registrant and afford opportunity to comply with chapter.—If it does not appear to the Commissioner that the pesticide is such as to warrant the proposed claims for it or if the pesticide and its labeling and other material required to be submitted do not comply with the provisions of this chapter, he shall notify the registrant of the manner in which the pesticide, labeling, or other material required to be submitted fails to comply with this chapter so as to afford the registrant an

opportunity to make the necessary corrections.

§ 3.1-249.44. When Commissioner may refuse or cancel registration.—The Commissioner may refuse to register, or may cancel the registration of, any brand of pesticide as provided in this chapter, upon satisfactory proof that the registrant has committed any of the acts prohibited by subsection A of § 3.1-249.63 of the Code of Virginia or any regulation promulgated by the Board for the enforcement of this chapter. No registration shall be revoked or refused until the registrant shall have been given a hearing by the Commissioner.

§ 3.1-249.45. When Board may refuse or cancel registration.—The Board may deny or cancel the registration of a pesticide if it finds, after a hearing that:

1. Use of the pesticide has demonstrated unreasonable adverse effects on the environment; or

2. A false or misleading statement about the pesticide has been made or implied by the registrant or the registrant's agent, in writing, verbally or through any form of advertising literature; or

3. The registrant has not complied or the pesticide does not comply with a requirement of this chapter or a regulation adopted under this chapter.

§ 3.1-249.46. Annual business license required.—A. No pesticide business may sell, distribute, or store any pesticide in Virginia without a valid pesticide business license issued pursuant to regulations promulgated by the Board. The Board shall promulgate regulations which exempt retailers of limited quantities of nonrestricted use pesticides including grocery stores, convenience stores, drug stores, veterinarians and other businesses who sell pesticides primarily for limited household use.

B. No person or business may apply or recommend for use commercially in Virginia any pesticide without a valid pesticide business license issued pursuant to regulations promulgated by the Board.

C. An annual business license and fee shall be required for each location or outlet that sells, distributes, stores, applies, or recommends for use any pesticide in Virginia unless otherwise exempt pursuant to the provisions of this section.

D. An application for a pesticide business license shall be submitted in such manner and form as prescribed by the Board.

§ 3.1-249.47. Fees.—An application for a pesticide business license shall be accompanied by a nonrefundable annual licensing fee established by the Board.

If a person or business fails to apply for renewal of a pesticide business license sixty days prior to expiration, the applicant, as a condition of renewal, shall pay a late license fee of twenty percent of the licensing fee in addition to that fee.

§ 3.1-249.48. Records.—As a condition of obtaining or renewing a license, each pesticide business required to be licensed shall maintain such records as required by the Board.

The Board may require a licensed pesticide business to submit records to the Board. Failure to submit a record requested by the Board is a ground for revocation of a license.

§ 3.1-249.49. Evidence of financial responsibility required of licensed pesticide business.—The Board shall not issue a pesticide business license until the business has furnished evidence of financial responsibility, consisting either of (i) a surety bond to the benefit of the Board from a person authorized to do business in Virginia or (ii) a liability insurance policy from a person authorized to do business in Virginia or a certification thereof, protecting persons who may suffer legal damages as a result of the use of any pesticide by the applicant. Such financial responsibility need not apply to damages or injury to agricultural crops, plants or property being worked upon by the applicant. In addition to a surety bond or a liability insurance policy, the Board, by regulation, may establish and prescribe the conditions under which other means of meeting the financial responsibility herein of the applicant may be met.

The amount of such financial responsibility as provided for in this section shall be established by the Board, but shall be at minimum, $200,000 for property damage, subject to a $1,000 deductible provision and $200,000 for personal injury. The Board may promulgate regulations governing the provision of additional evidence of financial responsibility based upon annual gross revenue of the applicant or his employer's business and an assessment of the risks of the applicant or his employer's business to persons, property and the environment. Such financial responsibility shall be maintained at not less than such amount at all times during the licensed period. The Board shall be notified ten days prior to any reduction at the request of the applicant or cancellation of such financial responsibility by the surety or insurer. If the applicant's deductible is other than $1,000, evidence of financial responsibility must be furnished to the Board to satisfy the difference between the applicant's deductible and the $1,000 deductible. This evidence may

be a financial statement, personal bond, or similar proof acceptable to the Board under regulations promulgated by the Board.

§ 3.1-249.50. Licensing of pesticide bulk storage facilities.—The Board shall establish, by regulation, specific requirements for the licensing of a pesticide business who mixes, stores or otherwise handles pesticides in bulk quantities. For purposes of this section bulk quantity shall not include containers approved for transportation in interstate commerce by the United States Department of Transportation.

Article 3.

Pesticide Application and Certification.

§ 3.1-249.51. Restricted use pesticides prohibited; exceptions.—No person shall use any pesticide classified for restricted use unless that person has first complied with the certification requirements of the Board or unless such person is acting under the direct supervision of a certified applicator.

§ 3.1-249.52. Application and certification of commercial applicators.—A. Application for a commercial applicator's certificate shall be made in writing to the Commissioner. Each application for a certificate shall contain information regarding the applicant's qualifications and proposed operations, the classification or classifications the applicant is applying for, and shall include the following: (i) the full name of the applicant or if the applicant is a member of a firm or partnership, the names of the principal officers of the association, corporation or group; (ii) the principal business address of the applicant in the Commonwealth and elsewhere; and (iii) any other information required by the Commissioner.

B. The Commissioner shall not issue a commercial applicator's or registered technician's certificate until the individual who uses or supervises the use of a pesticide, including those classified for restricted use, is certified by (i) presenting proof of completion of a training course approved by the Board and appropriate to the desired classification and (ii) passing a written examination.

C. An applicator shall be required to renew his certification biennially under the classification or subclassification for which such applicator is certified or technician is registered, subject to payment of the required fee and presentation of proof of completion of a Board approved recertification course. However, reexamination or special examination may be required by the Board of any person (i) whose certification has been suspended, revoked, or modified pursuant to subsection C of § 3.1-249.63, (ii) if significant technological developments have occurred requiring additional knowledge related to the classifications or subclassifications for which the person has been certified or registered, (iii) when required by additional standards established by the United States Environmental Protection Agency, (iv) when applying for a different classification of certification, including upgrading from technician to applicator status, or (v) when required by regulations of the Board. In the event that reexamination is required, the fee shall be no greater than that imposed for initial certification.

D. If the Commissioner finds the applicant meets the qualifications established by the Board to apply pesticides in any of the classifications he has applied for, and if the applicant is applying for a certificate to engage in aerial application of such pesticides and has met all of the requirements of the Federal Aviation Agency, the Department of Aviation of the Commonwealth, and any other applicable federal or state laws or regulations to operate the equipment described in the application, the Commissioner shall issue a certificate for classifications for which the applicant is qualified. The Commissioner may limit the certification of the applicant to the use of certain pesticides, or to certain areas, or to certain types of equipment if the applicant is only so qualified. If a certificate is not issued as applied for, the Commissioner shall, within thirty days, inform the applicant in writing of the reasons therefor. Copies of such action shall be reported to the Board.

§ 3.1-249.53. Agencies or persons exempt or partially exempt.—A. All state agencies, municipal corporations or other governmental agencies shall be subject to the provisions of this article and regulations adopted thereunder concerning the application of pesticides. These agencies shall be exempt from any certification fees prescribed by this article.

B. Individuals, employees or representatives certified pursuant to this section shall be certified commercial applicators for the use of pesticides covered by the applicant's certification. The certification of such individual shall be valid only when applying or supervising application of pesticides used by such governmental agencies.

C. The provisions of this article shall not apply to persons conducting research involving restricted use of pesticides nor to doctors of medicine or doctors of veterinary medicine applying pesticides as drugs or medication during the normal course of their

practice.

§ 3.1-249.54. Application and certification of private applicators.—A. No private applicator shall use any pesticide classified for restricted use unless the person has first obtained certification from the Commissioner in accordance with regulations promulgated by the Board. An applicator shall be required to renew his certification biennially under the classification or subclassification for which such applicator is certified.

Reexamination or special examination is required by the Commissioner of any applicator (i) whose certification has been suspended, revoked, or modified pursuant to § 3.1-249.63 or (ii) if significant technological developments have occurred requiring additional knowledge related to the classifications or subclassifications for which the applicator has applied or (iii) when required by additional standards established by the United States Environmental Protection Agency or (iv) when required by regulations of the Board. To obtain recertification, the applicator shall furnish satisfactory evidence of completion of educational courses, programs, or seminars approved by the Board relating to the applicator's certification.

B. The Commissioner shall, within thirty days, inform the applicant in writing of his decision.

§ 3.1-249.55. Certificate renewals; penalty for delinquent renewals; reexamination.—If the application for renewal of any certificate provided for in this article is not filed prior to a date established by the Board, a penalty of twenty percent shall be assessed and added to the renewal fee and shall be paid by the applicant before the renewal shall be issued. Such penalty shall not apply if the applicant furnishes an affidavit certifying that he has not engaged in the application of pesticides classified for restricted use subsequent to the expiration of his certificate. However, if the certificate is not renewed within sixty days following the expiration of the certificate, then such certificate holder shall be required to take another examination.

§ 3.1-249.56. Reports of pesticide accidents, incidents or loss.—A. The Board shall by regulation require the reporting of significant pesticide accidents or incidents which constitute a threat to humans or the environment to appropriate governmental agencies. To the extent feasible, the accident reporting requirements shall be consistent with similar reports required under other laws.

B. Any person claiming damages from the use or application of any pesticide classified for restricted use shall file with the Commissioner a written statement claiming that he has been damaged, within sixty days after the date that damages occurred. If a growing crop is alleged to have been damaged, the statement must be filed prior to the time that twenty-five percent of the crop has been harvested. Such statement shall contain, but shall not be limited to, the name of the person allegedly responsible for the application of such pesticide, the name of the owner or lessee of the property on which the crop is grown and for which damage is alleged to have occurred, and the date on which the alleged damage occurred. The Commissioner shall, upon receipt of such statement, notify the certificate holder and the owner or lessee of the property or other person who may be charged with the responsibility of the damages claimed, and furnish copies of such statements as may be requested. The Commissioner shall inspect damages where possible and his findings shall be made available to the parties.

The filing of such statement or the failure to file such statement need not be alleged in any complaint which might be filed in a court of law, and the failure to file the statement shall not be considered any bar to the maintenance of any criminal or civil action.

Where damage is alleged to have occurred, the claimant shall permit the Commissioner, the certificate holder and his representatives, such as bondsman or insurer, to observe within reasonable hours any plants, animals or other property alleged to have been damaged in order that such damage may be examined. Failure of the claimant to permit such observation and examination of the damaged property shall relieve the Commissioner of responsibility to take further action with reference to that claim.

§ 3.1-249.57. Reciprocal agreement.—The Commissioner may issue a certificate on a reciprocal basis with other states or federal agencies without examination in accordance with the provisions of this chapter or regulations, to a nonresident who is licensed or certified in another state or by a federal agency substantially in accordance with the provisions of this chapter. Such a certificate may be suspended or revoked in the same manner and on the same grounds as other certifications pursuant to the provisions of this article, and may be suspended or revoked if the nonresident's base state or federal certification is suspended or revoked.

§ 3.1-249.58. Enforcement.—A. For the purpose of carrying out the provisions of this chapter the Commissioner may enter upon any public or private premises at reasonable

times, with the consent of the owner or tenant thereof, in order: (i) to have access for the purpose of inspecting any equipment subject to this chapter, (ii) to inspect storage or disposal areas, (iii) to inspect or investigate complaints of injury to humans, animals, birds or property, (iv) to sample any pesticide being applied or to be applied, or (v) to enforce any other provision of this chapter.

B. Should the Commissioner be denied access to any premises where such access was sought for the purposes set forth in this chapter, he may apply for a search warrant which shall be granted if there is probable cause to believe that a criminal violation of this chapter exists.

Article 4.

Marine Antifoulant Paints.

§ 3.1-249.59. Definitions.—As used in this article, unless the context requires otherwise:

"Acceptable release rate" means a measured release rate not to exceed 4.0 micrograms per square centimeter per day at steady state conditions as determined in accordance with a U.S. Environmental Protection Agency (EPA) testing procedure as outlined in the EPA data call-in notice of July 29, 1986, on tributyltin in antifoulant paints under the Federal Insecticide, Fungicide and Rodenticide Act, (7 U.S.C. § 136 et seq.). If a lower release rate is determined by the Board to be necessary to protect health or the environment, such rate, if duly adopted by regulatory action of the Board, shall be the acceptable release rate as herein defined.

"Board" means the Pesticide Control Board.

"Commercial boat yard" means any facility which engages for hire in the construction, storage, maintenance, repair or refurbishing of vessels (other than seaplanes) or any licensed independent marine maintenance contractor who engages in such activities.

"Marine antifoulant paint" means any compound, coating, paint or treatment applied or used for the purpose of controlling freshwater or marine fouling organisms on vessels.

"Tributyltin compounds" means any compound having three normal butyl groups attached to a tin atom and with or without an anion such as chloride, flouride or oxide.

"Vessel" means every description of watercraft, other than a seaplane, used or capable of being used as a means of transportation on the water, whether self-propelled or otherwise, and includes barges and tugs.

§ 3.1-249.60. Sale and application of tributyltin compounds.—A. Except as otherwise provided in this section, a person may not distribute, possess, sell or offer for sale, apply or offer for use or application any marine antifoulant paint containing tributyltin compounds. Authorized personnel of the Commission of Game and Inland Fisheries, Virginia Marine Resources Commission, or the Department of Agriculture and Consumer Services may seize any antifoulant paint held in violation of this article and any seized substances shall be considered forfeited.

B. A person may distribute or sell a marine antifoulant paint containing tributyltin with an acceptable release rate to the owner or agent of a commercial boat yard. The owner or agent of a commercial boat yard may possess and apply, or purchase for application, an antifoulant paint containing tributyltin with an acceptable release rate; however, such paint may be applied only within a commercial boat yard and only to vessels which exceed twenty-five meters (82.02 feet) in length or which have aluminum hulls.

C. A person may distribute, sell or apply a marine antifoulant paint containing tributyltin having an acceptable release rate if the paint is distributed or sold in a spray can in a quantity of sixteen ounces avoirdupois or less and is commonly referred to as outboard or lower unit paint.

§ 3.1-249.61. Educational programs.—Through cooperative programs the State Water Control Board, the Board of Game and Inland Fisheries, the Virginia Marine Resources Commission, the Virginia Institute of Marine Science, and the Department of Agriculture and Consumer Services shall begin immediately to develop and implement a program designed to inform interstate and intrastate paint manufacturers and distributors, vessel owners and commercial boat yards in the Commonwealth of properties of tributyltin in marine antifoulant paints and the law to restrict its use.

§ 3.1-249.62. Emergency actions.—Nothing in this article is intended to prevent or discourage the Board from further restricting the distribution, possession, sale or use of tributyltin compounds.

Article 5.

Violations, Penalties and Proceedings in Case of Violations.

§ 3.1-249.63. Violations generally.—A. It shall be unlawful for any person to manufacture, distribute, sell or offer for sale, use or offer for use:

1. Any pesticide which is not registered pursuant to the provisions of Article 2 (§ 3.1-249.35 et seq.) of this chapter, or any pesticide if any of the claims made for it or any of the directions for its use differ in substance from the representations made in connection with its registration, or if the composition of a pesticide differs from its composition as represented in connection with its registration. In the discretion of the Commissioner, a change in the labeling or formula of a pesticide may be made, within a registration period, without requiring reregistration of the product; however, changes at no time are permissible if they lower the efficacy of the product.

2. Any pesticide sold, offered for sale, or offered for use which is not in the registrant's or the manufacturer's unbroken container, and to which there is not affixed a label visible to the public bearing the following information:

a. The name and address of the manufacturer, registrant, or person for whom manufactured;

b. The name, brand, or trademark under which said pesticide is sold; and

c. The net weight or measure of the content, subject to such reasonable variations as the Commissioner may permit.

3. Any pesticide which contains any substance or substances in quantities highly toxic to man, unless the label shall bear, in addition to any other matter required by this chapter:

a. A skull and crossbones;

b. The word "poison" prominently, in red, on a background of distinctly contrasting color; and

c. A statement of an antidote for the pesticide.

4. The pesticides commonly known as lead arsenate, basic lead arsenate, calcium arsenate, magnesium arsenate, zinc arsenate, zinc arsenite, sodium fluoride, sodium fluosilicate, and barium fluosilicate unless they have been distinctly colored or discolored as provided by regulations issued in accordance with this chapter, or any other white powder pesticide which the Commissioner, after investigation of and after public hearing on the necessity for such action for the protection of the public health and the feasibility of such coloration or discoloration, shall, by regulation, require to be distinctly colored or discolored, unless it has been so colored or discolored. The Commissioner may exempt any pesticide to the extent that it is intended for a particular use or uses from the coloring or discoloring required or authorized by this subsection if he determines that such coloring or discoloring for such use or uses is not necessary for the protection of the public health.

5. Any pesticide which is adulterated or misbranded, or any device which is misbranded.

6. Any pesticide that is the subject of a stop sale, use, or removal order as provided for in § 3.1-249.77 until such time as the provisions of that section have been met.

B. In addition to imposing civil penalties or referring certain violations for criminal prosecution the Board may, after providing an opportunity for a hearing, deny, suspend, modify, or revoke a license issued under this chapter if it finds that the applicant or licensee or his employee has committed any of the following acts, each of which is declared to be a violation:

1. Made false or fraudulent claims through any media, misrepresenting the effect of materials or methods to be utilized or sold;

2. Made a pesticide recommendation inconsistent with the label registered pursuant to this chapter, provided that such deviation may include provisions set forth in Section 2 (ee) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. § 136 et seq.);

3. Was guilty of negligence, incompetence or misconduct in acting as a pesticide business;

4. Made false or fraudulent records, invoices or reports;

5. Failed or refused to submit records required by the Board;

6. Used fraud or misrepresentation, or presented false information in making application for a license or renewal of a license, or in selling or offering to sell pesticides;

7. Stored or disposed of containers or pesticides by means other than those prescribed on the label or adopted regulation;

8. Provided or made available any restricted use pesticide to any person not certified, under the provisions of Article 3 (§ 3.1-249.51 et seq.) of this chapter, to apply such product;

9. Failed to notify the Department of a reportable pesticide spill, accident or incident.

C. The Board may after opportunity for a hearing, deny, suspend, revoke or modify the provision of any certificate issued under Article 3 (§ 3.1-249.51 et seq.) of this chapter, if it finds that the applicant or the holder of a certificate:

1. Has committed any of the following acts, each of which is declared to be a violation of the provisions of Article 3 (§ 3.1-249.51 et seq.) of this chapter:

a. Made claims through any media intentionally misrepresenting the effects on the environment likely to result from the application of a pesticide;

b. Used or caused to be used any pesticide inconsistent with the label registered by the United States Environmental Protection Agency, a Virginia state registered use or other uses restricted by the Board;

c. Made application of any pesticide in a negligent manner;

d. Neglected or, after notice, refused to comply with the provisions of this article, the regulations adopted hereunder or of any lawful order of the Commissioner or the Board;

e. Refused or neglected (i) to keep and maintain records or reports required pursuant to the provisions of Article 3 (§ 3.1-249.51 et seq.) of this chapter or regulations or (ii) to furnish or permit access for copying by the Commissioner any such records or reports;

f. Made false or fraudulent records, invoices or reports relative to the use or application of any pesticide;

g. Used or caused to be used any pesticide classified for restricted use on any property unless by or under the direct supervision of a certified applicator;

h. Used fraud or misrepresentation in making an application for a certificate or renewal of a certificate;

i. Refused or neglected to comply with any limitations or restrictions on or in a duly issued certification;

j. Aided, abetted, or conspired with any person to violate the provisions of Article 3 (§ 3.1-249.51 et seq.) of this chapter, or permitted one's certification or registration to be used by another person;

k. Impersonated any federal, state, county or city inspector or official; or

l. Made any statement, declaration or representation through any media implying that any person certified or registered under the provisions of Article 3 (§ 3.1-249.51 et seq.) of this chapter is recommended or endorsed by any agency of this Commonwealth.

2. Has been convicted or is subject to a final order assessing a penalty pursuant to § 14 (a) or (b) of the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. § 136 et seq.), as amended.

The Board, when deciding whether to deny, suspend, revoke, or modify any certificate or license, shall give due consideration to (i) the history of previous violations of the licensee or person, (ii) the seriousness of the violation including any irreparable harm to the environment and any hazards to the health and safety of the public, and (iii) the demonstrated good faith of the licensee or person charged in attempting to achieve compliance with the chapter after notification of the violation.

§ 3.1-249.64. Use of pesticide or container inconsistent with label directions or regulations of Board.—It shall be unlawful for any person to use or cause to be used any pesticide in a manner inconsistent with its labeling or regulations of the Board, provided that such deviation may include provisions set forth in Section 2 (ee) of the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. § 136 et seq.); and it also shall be unlawful to dispose of containers or unused portions of pesticide inconsistent with label directions or the regulations of the Board in the absence of label directions, or if those regulations further restrict such disposal.

§ 3.1-249.65. Alteration, etc., of label.—It shall be unlawful for any person to detach, alter, deface or destroy, in whole or in part, any label or labeling provided for in this chapter or the rules and regulations promulgated under this chapter.

§ 3.1-249.66. Refusal of access to records.—It shall be unlawful for any manufacturer, distributor, dealer, carrier, or other person to refuse, upon a request in writing specifying the nature or kind of pesticide or device to which such request relates, to furnish to or permit any person designated by the Commissioner to have access to and to copy such records of business transactions as may be essential in carrying out the purposes of this chapter.

§ 3.1-249.67. Giving false guaranty; names and addresses of persons giving and receiving guaranty.—It shall be unlawful for any person to give a guaranty or undertaking provided for in § 3.1-249.83 which is false in any particular, except that a person who receives and relies upon a guaranty authorized under such section may give a guaranty to the same effect, which guaranty shall contain in addition to his own name and address the name and address of the person residing in the United States from whom he received the guaranty or undertaking.

§ 3.1-249.68. Protection of trade secrets and other information.—A. In submitting data required by this chapter, the applicant may (i) clearly mark any portions thereof which in

his opinion are trade secrets or commercial or financial information and (ii) submit such marked materials separately from other material required to be submitted under this chapter.

B. Notwithstanding any other provision of this chapter, and subject to the limitations in subsections D and E of this section, the Commissioner shall not make public information which in his judgment contains or relates to trade secrets or commercial or financial information obtained from a person and privileged or confidential, except that, when necessary to carry out the provisions of this chapter, information relating to formulas of products acquired by authorization of this chapter may be revealed to any federal, state or local agency consulted and may be revealed at a public hearing or in findings of fact issued by the Commissioner or Board.

C. If the Commissioner proposes to release for inspection information which the applicant or registrant believes to be protected from disclosure under subsection B of this section, he shall notify the applicant or registrant, in writing, by certified mail. The Commissioner shall not thereafter make available for inspection such data until thirty days after receipt of the notice by the applicant or registrant. During this period, the applicant or registrant may institute an action in an appropriate circuit court for a declaratory judgment as to whether such information is subject to protection under subsection B.

D.1. All information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products, and any information concerning the effects of such pesticide on any organism or the behavior of such pesticide in the environment, including, but not limited to, data on safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation and fate in the environment, and metabolism, shall be available for disclosure to the public. The use of such data for any registration purpose shall be governed by Article 2 (§ 3.1-249.35 et seq.) of this chapter. This subsection does not authorize the disclosure of any information that:

a. Discloses manufacturing or quality control process,

b. Discloses the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide, or

c. Discloses the identity or percentage quantity of any deliberately added inert ingredient of a pesticide, unless the Commissioner has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment.

2. Information concerning production, distribution, sale, or inventories of a pesticide that is otherwise entitled to confidential treatment under subsection B of this section may be publicly disclosed in connection with a public proceeding to determine whether a pesticide, or any ingredient of a pesticide, causes unreasonable adverse effects on health or the environment, if the Commissioner determines that such disclosure is necessary in the public interest.

3. If the Commissioner proposes to disclose information described in subdivisions D1 a, b, or c or subdivision D2 of this section, the Commissioner shall notify by certified mail the submitter of such information of the intent to release such information. The Commissioner shall not release such information, without the submitter's consent, until thirty days after the submitter has been furnished such notice. Where the Commissioner finds that disclosure of information described in subdivisions D1 a, b, or c is necessary to avoid or lessen an imminent and substantial risk or injury to the public health, the Commissioner may set such shorter period of notice and such method of notice as the Commissioner finds appropriate. During such period the data submitter may institute an action in an appropriate circuit court to enjoin or limit the proposed disclosure. The court shall give expedited consideration to any such action. The court may enjoin disclosure, or limit the disclosure or the parties to whom disclosure shall be made, to the extent that:

a. In the case of information described in subdivision D1 a, b, or c, the proposed disclosure is not required to protect against an unreasonable risk of injury to health or the environment; or

b. In the case of information described in subdivision D2 of this section, the public interest in availability of the information in the public proceeding does not outweigh the interests in preserving the confidentiality of the information.

E. Information otherwise protected from disclosure to the public under subsection B of this section may be disclosed to contractors with the Commonwealth and employees of such contractors if, in the opinion of the Commissioner, such disclosure is necessary for the satisfactory performance by the contractor of a contract with the Commonwealth for the performance of work in connection with this chapter and under such conditions as the

Commissioner may specify. The Commissioner shall require as a condition to the disclosure of information under this section that the person receiving it take such security precautions respecting the information as the Board shall by regulation prescribe.

F. The Commissioner shall not knowingly disclose information submitted by an applicant or registrant under this chapter to any employee or agent of any business or other entity engaged in the production, sale, or distribution of pesticides in countries other than the United States or in addition to the United States or to any other person who intends to deliver such data to such foreign or multinational business or entity unless the applicant or registrant has consented to such disclosure. The Commissioner shall require an affirmation from any person who intends to inspect data that such person does not seek access to the data for purposes of delivering it or offering it for sale to any such business or entity or its agents or employees and will not purposefully deliver or negligently cause the data to be delivered to such business or entity or its agents or employees. Notwithstanding any other provision of this section the Commissioner may disclose information to any person in connection with a public proceeding under law or regulation, subject to restrictions on the availability of information contained elsewhere in this chapter, which information is relevant to the determination by the Commissioner with respect to whether a pesticide, or any ingredient of a pesticide, causes unreasonable adverse efects on health or the environment.

The Commissioner shall maintain records of the names of persons to whom data are disclosed under this section and the persons or organizations they represent and shall inform the applicant or registrant of the names and affiliation of such persons.

G. Any person, who, with intent to defraud, uses or reveals information relative to formulas of products acquired pursuant to this chapter shall be guilty of a Class 6 felony.

§ 3.1-249.69. Interference with Commissioner or agents.—It shall be unlawful for any person to oppose or interfere in any way with the Commissioner or his duly authorized agents in carrying out the duties imposed by this chapter.

§ 3.1-249.70. Penalties; action to enjoin violation; compromise.—A. Except as otherwise provided, any person who knowingly violates any provisions of this chapter or regulations promulgated hereunder shall be guilty of a Class 1 misdemeanor and shall be subject to an additional fine of up to $500,000 if death or serious physical harm to any person is caused by the violation.

B. The Commissioner may bring an action to enjoin the violation or threatened violation of any provision of this chapter, or any regulation made pursuant thereto, in the circuit court of the county or city in which the violation occurs or is about to occur, or in the Circuit Court of the City of Richmond if the violation may affect more than one county or city. The Commissioner may request either the attorney for the Commonwealth or the Attorney General to bring action under this section, when appropriate.

C. Any person violating a provision of this chapter or regulations adopted thereunder may be assessed a civil penalty by the Board. In determining the amount of any civil penalty, the Board shall give due consideration to (i) the history of previous violations of the licensee or person, (ii) the seriousness of the violation including any irreparable harm to the environment and any hazards to the health and safety of the public, and (iii) the demonstrated good faith of the licensee or person charged in attempting to achieve compliance with the chapter after notification of the violation.

D. The Board may assess a penalty of not more than $1,000 for a violation that is less than serious, not more than $5,000 for a serious violation, and not more than $20,000 for a repeat or knowing violation. The Board may assess an additional penalty of up to $100,000 for any violation which causes serious damage to the environment, causes serious injury to property, or serious injury to or death of any person.

E. Civil penalties assessed under this section shall be paid into a special fund in the state treasury to the credit of the Department to be used in carrying out the purposes of this chapter. The Commissioner shall prescribe procedures for payment of penalties which are not contested by licensees or persons. The procedures shall include provisions for a licensee or person to consent to abatement of the alleged violation and pay a penalty or negotiated sum in lieu of such penalty without admission of civil liability arising from such alleged violation.

Final orders of the Board may be recorded, enforced and satisfied as orders or decrees of a circuit court upon certification of such orders by the Commissioner. Such orders may be appealed in accordance with the provisions of the Administrative Process Act (§ 9-6.14:1 et seq.).

§ 3.1-249.71. Proceedings in case of violations.—A. If it shall appear from the examination of laboratory results or other evidence collected during an investigation that

any of the provisions of this chapter or the regulations issued thereunder have been violated, the Commissioner may cause notice of such violation to be given to the registrant, distributor, possessor, licensee, applicator or other person from whom such evidence was taken. Any party so notified shall be given an opportunity to be heard under such regulations as may be prescribed by the Board. If it appears after such hearing that there has been a violation of this chapter or the regulations issued thereunder, the Commissioner may certify the facts to the Board or the proper prosecuting attorney and furnish the Board or that officer with a copy of the results of such examination or investigation.

§ 3.1-249.72. Duty of attorney for Commonwealth.—It shall be the duty of every attorney for the Commonwealth to whom the Commissioner shall report any violation of this chapter to cause proceedings to be prosecuted without delay for the fines and penalties in such cases.

§ 3.1-249.73. Warning instead of report of violation.—Nothing in this chapter shall be construed as requiring the Commissioner to report for the institution of proceedings under this chapter, minor violations of this chapter, whenever the Commissioner believes that the public interest will be adequately served in the circumstances by a suitable written notice or warning. Copies of such warnings shall be reported to the Board.

§ 3.1-249.74. Exemptions from penalties.—The penalties provided for violations of § 3.1-249.63 shall not apply to:

1. Any carrier while lawfully engaged in transporting pesticides within this Commonwealth, if such carrier shall, upon request, permit the Commissioner or his designated agent to copy all records showing the transactions in and movements of the pesticides;

2. Public officials of this Commonwealth and the federal government engaged in the performance of their official duties in carrying out the provisions of this chapter and the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. § 136 et seq.) as amended;

3. Those individuals or agencies authorized by law to conduct research in the field of pesticides when such research is conducted in accordance with regulations established by the Board;

4. Any person who establishes a guaranty signed by, and containing the name and address of, the registrant or person residing in the United States from whom he purchased and received in good faith the pesticide in the same unbroken package, to the effect that the pesticide was lawfully registered at the time of sale and delivery to him, and that it complies with the other requirements of this chapter, designating this chapter. In such case the guarantor shall be subject to the penalties which would otherwise attach to the person holding the guaranty under the provisions of this chapter.

§ 3.1-249.75. Medicinal and toilet preparations, drugs or chemicals.—This chapter shall not apply to any preparation, drug, or chemical intended to be used or sold solely for medicinal use or for toilet purposes.

§ 3.1-249.76. Summary suspension by Commissioner; procedure.—The Commissioner may suspend the license of any person licensed or certified without a hearing simultaneously with the institution of proceedings for a hearing, if he finds there is a substantial danger to the public health, safety, or the environment which warrants this action. Institution of proceedings for a hearing shall be provided simultaneously with the summary suspension. The hearing shall be scheduled within a reasonable time of the date of the summary suspension.

Any licensee or certificate holder whose license or certificate has been suspended shall not engage in the activity for which he has been certified or licensed pending the hearing.

§ 3.1-249.77. "Stop-sale, use or removal" orders; judicial review.—The Commissioner shall issue and enforce a written or printed "stop-sale, use or removal" order directed to the owner or custodian of any lot of pesticide, requiring him to hold it at a designated place, when the Commissioner finds the pesticide is being offered or exposed for sale or use or is being used in violation of any of the provisions of this chapter, until the law has been complied with and the pesticide is released in writing by the Commissioner, or the violation has been otherwise legally disposed of by written authority. The owner or custodian of such pesticide shall have the right to judicial review of such order in accordance with the provisions of the Administrative Process Act (§ 9-6.14:1 et seq.). The provisions of this section shall not be construed as limiting the right of the enforcement officer to proceed as authorized by other provisions of this chapter. The Commissioner shall release the pesticide so withdrawn when the requirements of the provisions of this chapter have been complied with and upon payment of all costs and expenses incurred in connection with the withdrawal.

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§ 3.1-249.78. Seizure, condemnation and sale.—Any lot of pesticide not in compliance with the provisions of this chapter shall be subject to seizure on complaint of the Commissioner to a court of competent jurisdiction in the area in which the pesticide is located. In the event the court finds the pesticide to be in violation of this chapter and orders its condemnation, it shall be disposed of in any manner consistent with its quality and the laws of the Commonwealth; however, in no instance shall the disposition of the pesticide be ordered by the court without first giving the claimant an opportunity to apply to the court for the release of such pesticide or for permission to process, relabel, or otherwise bring it into compliance with this chapter.

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COPING WITH DELANEY'S PARADOX

Invited Testimony by
Charles M. Benbrook, Ph.D.
May 15, 1989

Before the
Subcommittee on Toxic Substances,
Environmental Oversight, Research and Development
Senate Committee on Environment and Public Works

I appreciate this opportunity to testify before the subcommittee. My name is Charles M. Benbrook. I am the Executive Director of the Board on Agriculture of the National Research Council. The NRC is the working arm of the National Academy of Sciences, National Academy of Engineering, and the Institute of Medicine.

The Board on Agriculture and NRC have a long history of studies on pesticide and agricultural policy. In 1987, the board completed a major EPA funded project on a particularly vexsome aspect of the pesticide regulatory system. Our report, entitled Regulating Pesticides in Food: The Delaney Paradox, assessed the regulatory and legal dilemma facing EPA as it tries to reconcile the conflicting standards that govern setting certain pesticide tolerances. In 1986 we released a report, Pesticides and Groundwater Quality: Issues and Problems in Four States. A major report was released in 1985 on pesticide resistance. In the late 1970s, the NRC undertook a comprehensive assessment of the pesticide regulatory process, and helped the EPA establish many of the scientific principles now incorporated in pesticide risk-benefit decision-making.

Our work is ongoing, as well. We will release this fall a comprehensive study on alternative agriculture, which examines options to pesticides and how some public policies have increased farmers' dependence on chemical control technologies. Incidentally, many of the key issues addressed in our forthcoming report were raised in last week's Wall Street Journal piece, "A Movement to Farm Without Chemicals Makes Surprising Gains." (A copy of this article is attached.) In partnership with the NRC's Board on Environmental Sciences and Toxicology, we also have under way a very important study examining the adequacy of current risk assessment methodologies in predicting the risks faced by infants and children from exposure to pesticides through food and water. I attach for the record a brief description of our ongoing study, "Scientific and Policy Issues Surrounding the Regulation of Dietary Exposure to Pesticides for Infants and Children". A report summarizing the results of this study will be released in the fall, 1990.

The Delaney Paradox

I would like to describe the issues analyzed in our 1987 report Regulating Pesticides in Food: The Delaney Paradox. I attach for the

record the report's table of contents and Executive Summary, and a list of the committee which carried out the study.

This report presented the first comprehensive analysis of the pesticide tolerance setting process and its impacts on the distribution of pesticide residues and "worst case" oncogenic risks in the diet. Chapter 3, "Estimates of Oncogenic Risks," contains a number of striking findings relevant to the policy issues and options before the agency, and under review this morning. I should note that legislation drafted by Congressman Henry Waxman and recently introduced in both houses ("The Food Safety Amendments of 1989," S. 722, Senator Kennedy; HR 1725, Congressman Waxman) rests largely upon the report's findings, and attempts to incorporate in legislation the report's principal recommendations.

The charge given in 1984 to the Delaney committee by EPA was to develop an analytical framework to assess the public health and agricultural impact of different approaches to setting food tolerances. We were asked, in particular, to focus on resolving the inconsistency between the zero-risk standard set by the Delaney Clause of the Food, Drug and Cosmetic Act and the risk-benefit balancing standard in the Federal Insecticide, Fungicide, and Rodenticide Act, or FIFRA.

Congressional oversight committees and EPA had by 1983 identified a number of specific pesticide regulatory cases in which the requirements of the two statutes appeared in conflict; and in which EPA felt compelled to take action (or, more commonly inaction) which either violated the standards and procedures of one statute or the other.

Delaney's Paradox first arose as EPA denied in the mid-1980s registrations for safer, new pesticides that posed very minute oncogenic risk (say 10^{-8}), yet left on the market other pesticides for the same use posing more risk (say 10^{-5} or higher).

The zero risk standard of the Delaney Clause would seemingly allow no food tolerance to be set for certain pesticides shown to cause tumors in laboratory animals. More by legislative construction than design, the zero-risk standard applies only to oncogenic pesticides for which residues concentrate in processed food above the level allowed in raw food. The Delaney Clause, an amendment to section 409 of the FDCA, does not have any practical impact on the residues of oncogenic pesticides on or in raw food unless the residues concentrate to higher levels in processed food. Tolerances to cover residues in fresh foods are set by EPA using a risk-benefit standard, under authority specified in section 408 of the FDCA. When residues concentrate and a pesticide is found to be an oncogen, then presumably the Delaney Clause would apply.

This obscure legal point has exacerbated controversies over EPA's regulation of several pesticides including daminozide, captan, the EBDC's, and benomyl. This is because the EPA is caught between a legal "rock" and a public health "hard place." While prudent public health policy would seem to warrant tolerance reductions for major food uses for pesticides like daminozide and captan, such actions would create difficult legal problems for the Agency. The legal problem would arise because lowering section 408 raw agricultural product tolerances will routinely -- but not

always -- create the need to establish some higher section 409 tolerance to cover concentrating residues in some processed foods. Alas, the Agency would be blocked by the Delaney clause from doing so when a pesticide has been found to cause cancer in man or animals. Accordingly, EPA has never used or seriously explored tolerance reductions as a separate administrative action. In the view of some legal experts, EPA lacks clear authority to lower -- as opposed to cancel -- tolerances. The legality of such actions has, in any event, never been tested by the Agency outside the context of a special review or cancellation action, accompanied by a complete dataset and risk-benefit finding that risks indeed exceed benefits. It takes years and tens of millions of dollars per pesticide in public and private costs to conduct a contested special review or cancellation action. In some cases like daminozide, the results are far from satisfying to all parties even after enormous investments in trying to determine the true magnitude of risk.

The committee which authored our Delaney Paradox report assembled a unique and powerful data base. It covers all pesticides registered for use on foods, and each crop use of each pesticide. It includes EPA data on food consumption, legal tolerances, and the carcinogenic potency of 28 pesticides. As new data on oncogenicity or reliable actual residue data become available, they can be incorporated into the data base. The data base is <u>not</u> appropriate, by itself, to conduct highly refined risk-benefit assessments on all pesticides and foods, a task which would have required much more detailed analysis than time allowed, and years to generate still missing data. Rather, the committee's goal was to gain understanding of the distribution of risk among pesticides and foods, and across types of tolerances and pesticides, based on the best information then available to EPA. The committee designed the data base as an analytical tool to assess the impact of different regulatory options or scenarios on the risks and benefits of pesticides. It was, and remains a powerful and reliable tool to estimate the consequences of alternative risk reduction strategies, including alternative definitions of negligible risk.

Using this data base the committee arrived at several important conclusions regarding the distribution of pesticide risk in the food supply, as well as insights into the most efficient way to reduce this risk. (Efficient in terms of minimizing the loss of benefits to agricultural producers in achieving a given degree of risk reduction.) Many of these observations seem relatively basic; however, they are very important in understanding where EPA can focus it's efforts in reducing potential oncogenic risk from pesticide residues in the diet. Although a few pesticides have been removed from the market since 1987, and several additional pesticides have been determined by EPA to pose oncogenic risks, the policy-related conclusions reached by our committee remain valid.

Major Findings in the Delaney Paradox Report

The most important overall finding of the committee is that most of the potential oncogenic risk from pesticides in the diet is accounted for by a relatively small number of pesticides and foods. The committee estimated that between 80 to 90 percent of all dietary oncogenic risk from pesticides arise from residues of about 10 pesticides in about 15 foods.

Not surprisingly, the committee also concluded that most crops, and most uses of oncogenic pesticides pose "worst case" dietary cancer risks far less than one-in-one million, the common benchmark used in quantifying a "negligible risk" standard. Accordingly, meeting a negligible risk standard will not cause the wholesale disruption of American agriculture feared by some individuals and organizations. Adjustments in cropping patterns and agricultural production practices necessary to reduce dietary pesticide risk to negligible levels will impact relatively few producers growing a small number of crops, and then only in certain regions where these crops are grown. Regardless of the pesticide regulatory strategy the nation opts for, negligible risk levels will be most difficult to meet in generally hot, humid fruit and vegetable producing regions where pest pressures, soil conditions, and climate result in the need for much higher than average reliance on pesticides.

In addition the committee found that:

- EPA has set about 8,500 distinct tolerances, each covering use of a specific pesticide on a single crop (or crop grouping, like different kinds of lettuce). (See Table 2-1, page 35, Regulating Pesticides in Food: The Delaney Paradox.)

- About 80 percent of total estimated "worst case" risk stems from residues in fresh foods, and about 20 percent from processed foods. Fungicides account for 55 percent of risk in fresh foods, and 78 percent of risk in processed foods. (See Table 3-10, page 69.)

- For 53 oncogenic pesticides, there were over 800 food uses with a corresponding processed food form, yet there were only 31 section 409 tolerances for these uses -- far below the number that could ultimately be needed to cover concentrating residues. (See Table 3-8, page 64.)

- About 90 percent of the total estimated "worst case" dietary oncogenic risk is from tolerances granted before 1978. (See Table 3-28, and Figure 3-4, pages 86-87.)

- In terms of volume applied, 90 percent of all fungicide applications, 60 percent of all herbicide applications, and 30 percent of all insecticide applications are made with oncogenic compounds.

The committee then analyzed four regulatory scenarios to judge their effectiveness in reducing risk. A detailed description of these scenarios is contained in the attached pages from the report that I have submitted for the record.

The principal findings of the committee's scenario analyses are that:

- A one-in-one million risk standard would reduce dietary oncogenic risk by well over 90 percent, and revoke or modify only about one-third of all current tolerances for oncogenic pesticides, if consistently applied to residues in raw and processed foods, new and old pesticides, and each type of pesticide.

- The Delaney Clause, because of its selective impact on processed foods, could at best, if strictly enforced as written, reduce risk by about 55 percent. This assumes EPA would also cancel all section 408 tolerances associated with crop uses on which residues concentrate, a practical necessity since there is rarely a full-proof way to separate out that portion of a crop grown for the fresh market from crops destined for processing. Moreover, in the process of achieving a 55 percent reduction in potential risk, the Agency would have to revoke many more tolerances on more crops than necessary through consistent adherence to a negligible risk standard.

Key Conclusions

The committee reached several other important conclusions. One of the most important is that current laws and regulations, and the way they are implemented, have resulted in glaring inconsistencies in the way residues -- and hence risks -- of old and new pesticides are regulated.

Most troubling is the new versus old pesticide problem: under current policy, a new pesticide is guilty until proven innocent, an old pesticide is innocent until proven guilty. In the case of trade-offs between new and old oncogenic pesticides this arises because EPA has applied the Delaney Clause only to new pesticides.

The EPA has deferred applying the Delaney Clause to old pesticides because of the burdensome standard under FIFRA and process which must be followed to cancel a pesticide use. The Delaney Clause may appear to compel action, but it provides EPA no tools to get the job done. EPA is forced to change pesticide registrations through the provisions of FIFRA. It cannot grant a registration until a tolerance is set; it cannot revoke a tolerance without canceling a corresponding registration. Ironically, the EPA has used the Delaney Clause to deny tolerances and registration of some very weakly oncogenic new pesticides that present risks as low as 1 in 100,000,000, while not using the same Delaney Clause to revoke tolerances of other oncogenic compounds with dietary risks over 1,000 times higher. In some cases studied by the committee the new, safer pesticides would have been direct substitutes for the more hazardous pesticides, and would have provided farmers with an opportunity to reduce risks to themselves and consumers. In light of these facts, it is hard to escape the conclusion that the Delaney Clause has fallen short of accomplishing its objectives in the regulation of pesticides.

Another significant but indirect result of this study was the realization on the part of EPA, FDA, farmers, and the food industry that very little good data existed on actual levels of pesticide residues in the food supply. The recent flap over daminozide (Alar), and the NRDC report

on pesticide risks faced by children shows how far we have to go in generating better data on food residues of pesticides, and how weak our data is on the actual extent and consequences of use of potentially worrisome pesticides. The whole issue of pesticide benefit assessment is, I am sorry to say, a jumbo size can of worms.

The response to our 1987 report was immediate and significant. It was, in many respects, surprising. Perhaps the most surprising result of our report was the almost immediate emergence of private residue testing services now used by thousands of food retailers across the country. The popularity of such programs indicates the willingness of retailers and consumers to pay for increased certainty in the safety of the food they eat. NRDC would, no doubt, acknowledge that the most surprising, and clearly unwarranted and unintended result of their 1989 report was action by several school districts to halt distribution of apples, until their safety could be verified.

EPA Implementation Activities

We would like to take this opportunity to comment on EPA's efforts to date in implementing our report's recommendations. On October 19, 1988 the EPA issued a notice in the Federal Register describing a detailed plan to implement the committee's recommendations. In general the Agency proposed to grant food tolerances for new oncogenic pesticides that meet a negligible risk standard, as recommended in our report. The agency was not as clear, however, about the application of this standard to current food tolerances for older oncogenic pesticides. No doubt Dr. Moore will update the subcommittee later this morning on when and how the EPA will amend existing registrations and tolerances on older pesticides that pose risks above a negligible level.

This is clearly significant because most oncogenic risk is from old pesticides. By only addressing the establishment of <u>new</u> tolerances and not clearly articulating a plan to reduce risk from <u>current</u> tolerances the agency has not demonstrated a convincing commitment to risk reduction. Leaving risk reduction to a re-registration process likely to last well into the next century continues to erode public confidence in the Agency. This is regrettable, and largely undeserved, since EPA is making steady progress in filling key data gaps, and could accelerate risk reduction through re-registration if it had new authority to conditionally reduce risks to negligible levels when and as necessary, pending receipt of complete datasets and final re-registration or cancellation actions.

An example may help the subcommittee understand this point. The first pesticide to which EPA applied its new Delaney policy is the widely used fungicide captan. Our report contains a brief case study of captan on pages 201-203. In 1985 EPA proposed to cancel most uses of captan based on worst case risk estimates, which were far above negligible levels. It deferred action, pending the receipt of more accurate data on actual food residue levels, data on how widely the chemical is used, and other aspects of the risk and benefit assessment. Data has since been gathered showing that actual food residues are, in fact, far below tolerance levels, and that actual risks are far less that indicated by a worst case analysis. In

February of this year, EPA issued its final decision to cancel some captan uses and retain other uses, based on this new data. I would like to note that without rendering judgment, serious questions can be raised about the analytical methods and assumptions EPA used in reaching the judgment that risks associated with the major uses of captan are not above a negligible level. These questions will no doubt be debated in the scientific community -- with a little prodding from lawyers -- as the EPA and/or Congress defines new policy for regulating pesticides in food.

EPA's final decision on captan proposes to cancel 42 uses of captan, while retaining 24 others. While reducing potential risk substantially, a closer look raises many questions about the outcome of this decision.

First, nearly all of the canceled uses of captan were on crops where the agency had little evidence of captan use. In general between 0 and 10 percent of the acres of these crops were treated in any given year with captan. Canceling uses of a pesticide on crops where it is not used is not likely to result in significant actual risk reduction.

This decision may also have the unintended effect of <u>increasing</u> the oncogenic risk from fungicide residues on certain crops. In the absence of captan, other more hazardous fungicides may be used in the years when a disease outbreak warrants treatment. In fact, for many of the canceled uses, other oncogenic fungicides of <u>greater</u> oncogenic potency are listed as likely substitutes by EPA, and are still registered. Further, while the residues of captan are reduced with washing, some of the more potent oncogenic alternatives and their breakdown products are not removed with washing.

Second, none of the major uses of captan were canceled, nor were any of the tolerances covering these uses lowered toward a negligible risk level. EPA based this decision on estimates that no individual crop presents a greater than negligible risk when risk is calculated using a new methodology reliant on FDA monitoring data as the basis for exposure estimates. Moreover, because EPA generally calculates risk and exposure on a nationwide basis the method used in this case to calculate exposure may actually underestimate exposure and risk to regional subpopulations living in areas where fresh fruits and vegetables are often treated with captan.

Summary

The EPA faces a daunting task in regulating pesticides. Public concerns are clearly rising and are likely to continue growing as more is learned about the presence of pesticide residues in the food supply. The science of toxicology is advancing, particularly in new areas like immunotoxicity and neurotoxicity, and in estimating risks faced by special population. groups like infants, the elderly, and chronically ill individuals. A new generation of pest control technologies is emerging, which pose new challenges for EPA.

It is increasingly evident that the nation's pesticide regulatory laws and programs are not up to the task. Solutions that deal with fundamental issues and concerns will be politically contentious, will pose high short-run costs on some farmers and chemical companies, but if crafted wisely need not increase consumer food costs, nor adversely affect the availability of produce. I hope this Subcommittee will use the record of this hearing in the search for sound solutions. Thank you for the invitation to appear before the Subcommittee this morning.

United States General Accounting Office

GAO Testimony

For Release
on Delivery
Expected at
9:30 a.m. EDT
Monday,
May 15, 1989

Reregistration and Tolerance Reassessment Remain Incomplete for Most Pesticides

Statement of
Peter F. Guerrero, Associate Director
Environmental Protection Issues,
Resources, Community, and Economic
Development Division

Before the
Subcommittee on Toxic Substances, Environmental
Oversight, Research and Development
Committee on Environment and Public Works
United States Senate

GAO/T-RCED-89-40

Mr. Chairman and Members of the Subcommittee:

Three years ago we reported on the Environmental Protection Agency's (EPA) lack of progress in assessing and regulating the risks of existing pesticides and their allowable residues on food. In that report entitled PESTICIDES: EPA's Formidable Task to Assess and Regulate Their Risks (GAO/RCED-86-125, April 18, 1986), prepared at the request of members of the Committee, we made recommendations to accelerate and improve EPA's reregistration program. In response to the concerns we raised in that report, as well as concerns raised by others, the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1988 (which I will refer to as FIFRA '88) were enacted to help accelerate the reregistration of older pesticides.

My purpose today is to talk about what progress EPA has made since we issued our 1986 report. EPA is still at a preliminary stage in assessing the risks of older pesticides but it has made some progress. In reregistering about 35,000 pesticide products and reassessing about 6,000 tolerances for residues of these pesticides on food and feed, EPA's approach is to assess the effects of the products' approximately 822 active ingredients--those that destroy or control the pest.[1] (Hereafter, I will use the terms "active ingredients" and "pesticides" interchangeably.)

Our follow-up work shows that EPA has not completely assessed any of the 822 pesticides subject to reregistration but is close on at least three. Thus, it has not completed all product reregistration actions for any pesticide although it has reregistered some products. In addition, EPA has been able to completely reassess the safety of pesticide residues on food for only 4 of the approximately 387 food-use pesticides subject to

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[1]These numbers are approximate. EPA expects that many registrants will cancel a significant number of pesticide product registrations because of the fees and other requirements imposed by FIFRA '88.

reregistration because of gaps in knowledge about the toxicity and exposure of most food-use pesticides. EPA has completed all tolerance actions for 3 of these 4 pesticides.

In recent years, EPA has made limited progress in gathering data on major food-use pesticides. In 1986, we reported that EPA had developed 124 preliminary assessments of the 600 pesticides then subject to reregistration and had not completed a final assessment for any pesticide. Since that time, EPA has developed 70 more preliminary assessments for a total of 194.

While FIFRA '88 will help accelerate EPA's review of older pesticides, reregistering pesticide products and reassessing tolerances remain formidable tasks. In this regard I will discuss certain unresolved issues that complicate EPA's reregistration efforts, such as how EPA plans to reregister individual pesticide products.

Mr. Chairman, as part of my testimony this morning I will present two charts that depict EPA's progress in reregistering pesticides and reassessing the safety of pesticide residues on food. We believe these two charts will help the Congress monitor EPA's implementation of FIFRA '88.

FEDERAL PESTICIDE REGULATION

Federal regulation of pesticides is governed by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). Under FIFRA, a pesticide product must generally be registered by EPA before it may be marketed if EPA determines that its benefits outweigh its risks. Registrations are basically licenses for specific uses of a pesticide product that state the terms, conditions, and cautions of these uses. EPA requires pesticide product registrants and applicants to submit health and environmental effects data to

support product registrations. FIFRA also authorizes EPA to deny a new registration or restrict, cancel, or suspend an existing registration if it finds that a pesticide product presents an unreasonable risk to human health or the environment.

About 35,000 to 40,000 pesticide products, formulated from one or more active and inert ingredients, are currently registered.[2] According to EPA's May 3, 1989 estimate, approximately 3 billion pounds of pesticides are produced in the United States each year.

Under FFDCA, EPA must either establish a tolerance or grant a tolerance exemption[3] for each registered use of a pesticide on a food or feed crop. A tolerance is the maximum legal limit of pesticide residue allowed to remain in or on raw agricultural commodities, processed foods, or animal feed. It also represents an amount that is considered to impose no health hazard within a practical certainty over a lifetime of daily exposure. According to EPA, about 387 pesticides are registered for food uses, with about 6,000 tolerances for residues of these pesticides on numerous crops and processed foods.

RISKS OF MOST PESTICIDES REMAIN UNCERTAIN

Every man, woman, and child in the United States is exposed to pesticide residues in the food he or she eats. In a 1987 comparative risk report, EPA concluded that pesticide residues in

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[2]An active ingredient is the component in a pesticide product that is intended to specifically control or destroy a pest. An inert ingredient is not intended to control or destroy a pest, but rather is used to dissolve, dilute, propel, or stabilize the active ingredient in the pesticide product.

[3]EPA may grant an exemption from the requirement of a tolerance when it determines that a tolerance is not necessary to protect the public health. For example, EPA has exempted some naturally occurring substances not considered toxic to humans.

food rank among the top contributors to human health risks that it must regulate. However, the risks of most pesticides remain uncertain. The uncertainty of pesticide risks is not a new problem, only a persistent one.

As we have reported since 1975,[4] most pesticides were registered and most tolerances were established with much less data than are now required, resulting in the need to reregister these pesticides according to current data requirements and scientific standards. Since 1947, when FIFRA was first enacted, the range of concerns about the risks of pesticides has expanded to include potential chronic health effects, such as cancer and reproductive effects; adverse ecological effects; and the environmental fate of pesticides. The Congress amended FIFRA several times since 1947 to address these concerns. However, new data requirements dealing with these concerns were applied primarily to new pesticides or new uses--there was no systematic process to impose requirements retroactively on previously registered pesticide products. In addition, even for pesticides already tested, EPA has determined that certain studies were conducted using scientific standards no longer considered acceptable or were invalidly conducted and will need to be repeated or replaced.

HISTORY OF REREGISTRATION

As you know Mr. Chairman, reregistration has had a somewhat difficult and troublesome past. The 1972 amendments to FIFRA required EPA to reregister all previously registered pesticides by October 21, 1976. However, this task proved to be a much more extensive and time-consuming effort than first envisioned. In 1978, after EPA's early attempts to reregister pesticide products were unsuccessful, the Congress reaffirmed the need for EPA to

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[4] Federal Pesticide Registration Program: Is It Protecting The Public And The Environment Adequately From Pesticide Hazards? (RED-76-42, Dec. 4, 1975).

expeditiously reregister all pesticide products, required EPA to give priority to food-use pesticides, and deleted the deadline. The 1978 amendments also sanctioned a chemical-by-chemical approach rather than a product-by-product approach to reregistration; that is, the Congress gave EPA authority to make broad regulatory decisions at one time for all pesticide products containing the same active ingredient.

Although FIFRA does not specifically require EPA to reassess tolerances, EPA decided in 1977 to reassess tolerances for food-use pesticides through its reregistration program. Tolerance reassessment is a key component of the reregistration of pesticides used on food.

The Registration Standards Program has been EPA's major effort to systematically develop a comprehensive regulatory position for each pesticide. A registration "standard" describes all the data available on a particular pesticide, identifies data that are missing or inadequate, addresses regulatory and scientific issues for which sufficient data exist, and sets forth the conditions that pesticide products affected by the standard must meet to obtain or keep their registrations.

REREGISTRATION IS A FORMIDABLE TASK

Reregistration is the process of bringing the registrations of about 35,000 pesticide products and 6,000 pesticide tolerances into compliance with current data requirements and scientific standards and taking appropriate regulatory action on the basis of this new knowledge. To accomplish this task, EPA must review industry-submitted health and environmental studies and make regulatory decisions on the risks and benefits of pesticides registered over the past four decades. Industry must conduct the required tests for reregistration, some of which take up to 4 years to perform.

In the interim, previously registered pesticide products may be sold and distributed under their existing registrations.

We concluded in 1986 that, despite progress, EPA was at a preliminary stage in assessing the risks of existing pesticides. Further, we determined that without intervention EPA would not completely assess all older pesticides and tolerances until well into the 21st century because of the magnitude and complexity of the tasks involved, EPA's approach to reregistration, and EPA's resource limitations. In particular, we found the following:

-- EPA had not completed a final assessment on any pesticide because of data gaps. EPA had completed preliminary assessments of 124 of the 600 pesticides that were then subject to reregistration. Although EPA generally referred to them as registration standards, the 124 standards developed on pesticides through March 1986 were interim, not final, standards. About one-third to one-half of the data needed for final assessment were nonexistent or inadequate when EPA prepared the interim standards. However, EPA's review of available data on about 60 percent of the interim registration standards identified health and environmental concerns that necessitated additional restrictions, mostly labeling changes.

-- EPA had been unable to completely reassess the tolerances in 84 of the 92 interim registration standards for food-use pesticides that we reviewed, because required chronic toxicity and/or residue chemistry data were missing or inadequate. (EPA had sufficient data to reassess tolerances in eight interim standards.)

-- While EPA had accelerated its requests for chronic health effects and other data needed for reregistration, EPA had

not evaluated the adequacy of data already on file by contemporary data requirements and scientific standards.

-- At the time of our report, EPA had not been routinely following up on registrants' compliance with interim registration standard requirements, such as data and labeling requirements. About 50 percent of registrants' responses to interim registration standard requirements, including labeling changes designed to reduce health and environmental risks, were overdue. Moreover, EPA had not canceled any pesticide products for noncompliance with labeling requirements imposed by interim standards because of costly and time-consuming cancellation procedures under FIFRA.

We presented several options for the Congress to consider to accelerate pesticide reregistration and tolerance reassessment which are embodied in principle in FIFRA '88, including:

-- shifting some of the regulatory burden to industry by requiring industry, rather than EPA, to identify data gaps and assess the adequacy of existing data prior to EPA's assessment of the pesticide,

-- establishing reasonable deadlines for pesticide firms to submit complete test data and for EPA to review the data, and

-- providing additional resources to EPA to accelerate the reregistration process, possibly through user fees.

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WHAT FIFRA '88 REQUIRES AND WHEN

The Congress, through the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1988, significantly refocused EPA's reregistration program.[5] In our 1988 transition series report on EPA issues, we concluded that extraordinary leadership is needed to meet the new congressional mandates because EPA has not been successful in meeting deadlines or implementing pesticide reforms in the past.[6]

FIFRA '88 imposes mandatory time frames and duties, for both EPA and registrants, for reviewing the adequacy of the data required for reregistration. Over approximately a 9-year period, EPA must reregister each pesticide product containing any active ingredient contained in any pesticide product first registered before November 1, 1984, or take other appropriate regulatory action, such as canceling, suspending, or restricting the use of the pesticide. In addition, FIFRA '88 establishes a fee system expected to raise approximately $160 million over the 9 years to help fund the costs of accelerated reregistration.[7]

FIFRA '88 mandates that the accelerated reregistration scheme be carried out in five phases.

-- Phase 1: EPA must list the names of the active ingredients subject to reregistration in four installments by October 24, 1989. On February 22, 1989, EPA published

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[5]The President signed FIFRA '88 on October 25, 1988. The major provisions of FIFRA '88 became effective on December 24, 1988.

[6]Environmental Protection Agency Issues (GAO/OCG-89-20TR, Nov. 1988.)

[7]The fee provisions provided under FIFRA '88 expire on September 30, 1997.

the first installment, a list (List A) of active ingredients for which registration standards had been issued as of December 24, 1988. On April 24, 1989, EPA issued the second installment, a list (List B) of the first 150 active ingredients for which registration standards had not been issued prior to December 24, 1988. The third and fourth installments (Lists C and D) are not due until later this year. List C, the next 150 active ingredients subject to reregistration, is due on July 24, 1989. List D, the remainder of active ingredients subject to reregistration, is due on October 24, 1989.

-- Phase 2: The registrants of products containing each active ingredient identified on Lists B, C, and D must notify EPA of their intent to seek reregistration within 3 months after EPA publishes each list. If a registrant does not notify EPA or decides not to seek reregistration, EPA may cancel the relevant product registrations. Registrants must identify missing and inadequate studies required to satisfy EPA current data requirements, formally agree to submit new or replacement studies, and pay the first portion of a reregistration fee.

-- Phase 3: Lists B, C, and D registrants are required to summarize and reformat key existing studies, certify access to laboratory study records, identify studies that indicate adverse effects, commit to generate or share the cost of missing or inadequate studies, and pay the final portion of the reregistration fee. Registrants are required to submit the required information within 12 months after EPA publishes each list.

-- Phase 4: EPA is required to review the data and information that List B, C, and D registrants submitted during Phases 2 and 3, identify data gaps independently,

and notify registrants of these gaps. EPA is required to complete this phase within the time periods specified in FIFRA '88. (Assuming EPA publishes List D on time, EPA is required to complete Phase 4 by July 24, 1992.)

-- Phase 5: EPA is required to conduct a thorough, comprehensive examination of all data submitted in support of pesticide reregistration. On the basis of this review, EPA is required to either reregister individual pesticide products or take other appropriate regulatory action. According to EPA, this phase will occur over a span of approximately 3 to 9 years, depending on the scheduling of individual pesticides, the complexity of the required studies, and the time required for registrants to complete these studies.

List A represents most of the major food-use pesticides and the expeditious reregistration of these pesticides is paramount to reducing the uncertainty surrounding the risks of pesticides that leave residues on the food we eat. EPA announced in its April 20, 1989, FIFRA '88 implementation plan that it is developing a system and schedule for completing reregistration of the List A pesticides as soon as possible within the 9 years provided. However, there are several factors that may affect EPA's timely reregistration of List A pesticides. Although FIFRA '88 shifts some of the burden to the registrants to determine what is required to accomplish reregistration of any of their pesticides included on Lists B, C, and D, EPA is still responsible for determining what is required for pesticides on List A. Also, FIFRA '88 sets the fee schedule and interim deadlines for developing a complete data base for List B, C, and D pesticides, but leaves it to EPA's discretion to set the fee schedule and data development schedules for List A pesticides. Thus, it is important that EPA set the fee and data development schedules without delay to expeditiously reregister List A pesticides.

STATUS OF PESTICIDE REREGISTRATION
AND TOLERANCE REASSESSMENT

We have prepared two charts that depict EPA's progress in reregistering pesticides, and reassessing pesticide tolerances. We believe these charts will help the Congress monitor EPA's progress in implementing FIFRA '88. In the relatively brief amount of time we have had to prepare for this hearing, we have limited our update to the status of pesticides undergoing reregistration and tolerance reassessment. We did not attempt to update other material and issues contained in our 1986 report.

I would like to briefly discuss the charts in attachments I and II, respectively. Attachment I presents the status of pesticides undergoing reregistration, and attachment II presents the status of tolerance reassessment as of April 1989. Before beginning I would note that we obtained this information from EPA and did not independently verify the data. Further, I want to mention that both reregistration and tolerance reassessment are continuing processes which reports of this kind can only capture the status momentarily.

Status of Pesticides
Undergoing Reregistration

Mr. Chairman, if I may direct your attention to the first chart (attachment I), I will cover the status of pesticides undergoing reregistration.

-- Line 1 shows the total estimated number of pesticide products and active ingredients subject to reregistration. According to EPA, approximately 1,300 active ingredients are used in pesticide products subject to reregistration.

Although the active ingredients are counted equally for the purposes of this update, the importance of each active ingredient undergoing reregistration, in terms of human health and environmental protection, is not equal. This is because the production, use, toxicity of, and exposure to pesticides vary. Further, the degree of completion of each step in the reregistration process varies by active ingredient.

-- Line 2, box 1 shows the number of active ingredient groups--which EPA now refers to as "cases"--subject to reregistration. EPA has combined the approximately 1,300 individual active ingredients into about 822 cases containing active ingredients with similar chemical characteristics. The exact number of active ingredient cases subject to reregistration will not be known until EPA issues the last list of pesticide active ingredients subject to reregistration (List D) on October 24, 1989, as required under FIFRA '88.

EPA expects that about 600 active ingredient cases will undergo reregistration because registrants of products containing some active ingredients may decide not to pursue reregistration. EPA may have a better idea of the actual number of active ingredient cases that will undergo reregistration when the last of the registrants notifies EPA of its intent to seek reregistration. This information will be known around January 24, 1990, as required under FIFRA '88. We note that 822 is different from the number we and others have reported in the past. The difference is primarily due to the increased number of active ingredients subject to reregistration under FIFRA

'88[8] and to EPA's regrouping of the active ingredients. While 600 may be the number of cases that will ultimately undergo reregistration review, we believe it is prudent to use 822 until EPA has a clearer picture on registrants' intentions to pursue reregistration.

-- Line 2, box 2 represents the number of pesticides in special review. As of April 28, 1989, 17 pesticides were in special review. The special review process is an informal review process to evaluate the risks and benefits of pesticides of concern and determine whether regulatory action, such as canceling, suspending, or restricting a pesticide use, is needed. Pesticides in special review are also subject to reregistration.

-- Line 3, box 1 represents the approximate number of pesticides that registrants have canceled voluntarily or EPA has suspended. The number of cancellations and suspensions is uncertain because of limitations in EPA's data systems, especially in tracking recent registrant actions in response to the fees imposed under FIFRA '88.

-- Line 3, box 2 represents the List A pesticides. EPA had issued 194 registration standards as of December 24, 1988. These standards are really "interim" registration standards because EPA lacked sufficient information to fully assess the pesticide and its tolerances, at the time the standards were developed. This list represents most of the major food-use pesticides.

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[8]Prior to FIFRA '88, EPA was planning to reregister pesticide products containing active ingredients first registered before January 1, 1977. FIFRA '88 requires EPA to reregister each pesticide product containing any active ingredient contained in any pesticide product first registered before November 1, 1984, or take other appropriate regulatory action.

-- Line 3, box 3 represents List B, which is a list of the first 150 pesticides for which registration standards had not been issued prior to December 24, 1988, as required by FIFRA '88.

-- Line 3, box 4 shows that about 408 pesticides are candidates for Lists C and D.

-- Line 4, box 1 represents the number of pesticides that have been canceled or suspended following issuance of an interim registration standard. In the future, fewer pesticides may drop out after EPA has expended the resources developing registration standards. This is because FIFRA '88 requires registrants to declare their intentions to seek reregistration and pay fees before EPA has made this expenditure.

-- Line 4, box 2 shows that EPA has completed 18 second-round reviews,[9] which EPA previously called Final Registration Standards and Tolerance Reassessments. In a second-round review, EPA reviews any new data it has received since issuing the interim standard, updates its scientific and regulatory conclusions concerning the pesticide--including tolerances, if applicable--and identifies any additional data required to support reregistration. EPA changed the name of these reviews because it found that instead of being final assessments as planned, most of the second-round reviews have identified a number of new data gaps and EPA has had to postpone reregistration decisions on products containing the active ingredient until additional data are received and reviewed. According to EPA, new data may be required in a second-round review because of results of "tier" testing (in which the results of one study

[9]Of these 18, 4 are draft documents.

indicate the need for additional testing), revised data guidelines, new data requirements, inadequate studies submitted by registrants, and the need for additional data to support uses registered since the interim standard was issued.

-- Line 4, box 3 shows that 152 interim registration standards await second-round review. EPA plans to conduct an inventory of the data available for each List A pesticide for which a second-round review has not been completed to help expedite reregistration actions for these pesticides. During the inventory, EPA plans to assess the completeness and adequacy of the database for each pesticide, call in outstanding data, identify data for priority review, schedule future second-round reviews, and take appropriate compliance action on overdue data. EPA plans to complete the inventory in summer 1989.

-- Line 5 represents the bottom-line results of our efforts to update our 1986 report at the request of this Subcommittee. According to the Chief, Reregistration Branch, EPA has not completed a final assessment on any pesticide, but is close on at least three pesticides. Our review of the 18 second-round review pesticides indicates that EPA lacks sufficient data to completely assess the risks associated with most of these 18 pesticides. EPA's second-round reviews imposed, on average, about 50 data requirements for each pesticide, some necessitating studies that will take 4 years to complete, and others only a few months. Reregistration assessment of three pesticides is essentially complete (Heliothis zea NPV, sodium and calcium hypochlorite salts, and methoprene). I should point out that while none of the three have technically been through a second-round review EPA considers its regulatory position for these three to be essentially complete.

-- As Line 6 shows, EPA has not completed all product reregistration actions for any pesticide. However, according to EPA officials, they have reregistered some pesticide products but the number reregistered was not available at the time we performed our work.

That updates the information we have on the status of pesticides undergoing reregistration.

Status of Tolerance Reassessment

If I may now direct your attention to the second chart (attachment II), I will cover the status of EPA's tolerance reassessment efforts.

-- Line 1 shows the estimated number of tolerances and food-use active ingredients that will undergo tolerance reassessment. EPA estimates that 387 active ingredients have food uses subject to reregistration and tolerance reassessment. The exact number of food-use active ingredients that will undergo tolerance reassessment is uncertain because registrants of products containing some food-use active ingredients may decide not to pursue reregistration. Also, EPA may determine that some non-food-use active ingredients may need to be reclassified as food-use active ingredients requiring tolerance reassessment. This latter group may include pesticides whose uses were not regarded as food uses at the time of registration but have subsequently been reclassified as food uses. For example, in its second-round review of warfarin, a rodenticide, EPA determined that residue data are needed to support an existing use of warfarin as a tracking powder in food establishments.

-- Line 2 shows that EPA has determined, for all food-use pesticides, whether any chronic toxicolcgy studies were missing and, if so, notified registrants to submit the studies.

-- Line 3, box 1 shows that approximately 40 food-use pesticides have been canceled or suspended.

-- Line 3, box 2 shows that EPA has developed interim registration standards (List A) for 167 food-use pesticides.

-- Line 3, box 3 shows that there are about 180 food-use pesticides that are candidates for Lists B, C, and D. FIFRA '88 gives priority treatment to pesticides used on food or feed.

-- Line 4, box 1 shows that 14 food-use pesticides for which EPA had developed interim registration standards have been canceled or suspended.

-- Line 4, box 2 shows that EPA has developed 18 second-round reviews, all of which contain food uses.

-- Line 4, box 3 shows that 135 food-use pesticides await second-round review. These pesticides will be included in the inventory program I discussed earlier.

-- Line 5, box 1 shows that only four pesticides have completed tolerance reassessment (sodium and calcium hypochlorite salts, Heliothis zea NPV, methoprene, and fosetyl-al (Aliette)). For the other 14 (line 5, box 2) of the 18 second-round review pesticides, EPA lacks sufficient chronic toxicology or residue chemistry data to complete

tolerance reassessment. Some of these studies take up to 4 years to complete.[10]

-- Line 6 shows that EPA has completed all tolerance actions for 3 of the 4 pesticides for which tolerance reassessment is complete.

The bottom line on both charts is that EPA has made some progress to reregister pesticides, and reassess pesticide tolerances. However, EPA still has a long way to go.

UNRESOLVED ISSUES COMPLICATE REREGISTRATION

A number of unresolved pesticide regulatory issues further complicate reregistration and tolerance reassessment.

EPA needs to establish procedures for reregistering individual products. As we reported in 1986, developing a final assessment on an active ingredient case does not complete reregistration. EPA will have to apply decisions reached on each active ingredient to all individual products containing that ingredient, including products that contain multiple active ingredients, and take appropriate reregistration action on each product. The situation remains essentially unchanged today. EPA's plan for implementing FIFRA '88 does not specify how EPA will reregister pesticide products after it assesses an active ingredient. EPA has invited

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[10]In 1986, we reported that 8 of 92 interim standards we reviewed had completed tolerance reassessment. Four of the original eight that we reported as complete are still complete. For the other four, two have not undergone a second-round review or its equivalent and the other two have been subject to additional data requirements following the second-round review because new uses were added to the pesticide since the time the interim registration standard was issued. We did not determine the status of tolerance reassessment for the remaining interim registration standards for food-use pesticides that have been issued since we prepared our report.

comments on how this shall be achieved. Until this issue is resolved, it is unclear when reregistration will have been achieved and whether the requirements of FIFRA '88 have been met.

EPA needs to keep its "final" regulatory assessments of pesticides current because of the dynamic nature of pesticide regulation. Once EPA develops a "final" assessment for a pesticide, it may have to update and/or amend it to reflect changes in pesticide uses, composition, and formula not covered by the assessment; advancements in science and technology; new data of a type not previously required (e.g., neurotoxicity); and new information, or a reinterpretation of data, indicating significant human health or environmental concerns. Indeed, EPA's own experience with second-round reviews strongly suggests that EPA's pesticide regulatory assessments will never be "final" per se, nor should they be. EPA's FIFRA '88 implementation plan does not specify how this will be accomplished. However, keeping final regulatory assessments current will be a critical cost of doing business if EPA is to avoid costly and long-term efforts to periodically reregister pesticide products to bring them into compliance with evolving requirements, science, and uses.

EPA needs to enforce label requirements imposed through interim registration standards. In 1986, we reported that EPA had not canceled any pesticide product for noncompliance with labeling requirements imposed by interim standards, though several products were not in compliance. We recommended that the Administrator cancel product registrations whose labels are not in compliance with registration standard requirements and, if necessary, pursue legislative changes to provide statutory authority to more efficiently implement label requirements. EPA agreed with our recommendation and eventually canceled one product for label noncompliance. However, in December 1988, EPA informed us that it has not pursued additional cancellation actions because of the cumbersome and time-consuming cancellation procedures under FIFRA

section 6. According to the Director, Policy and Special Projects Office, EPA does not have the authority it believes it needs to impose needed label changes in an expeditious manner. EPA informed us that it remains receptive to a legislative solution to this problem and has raised this issue in testimony before the Subcommittee on Department Operations, Research and Foreign Agriculture, House Committee on Agriculture. We believe the recommendation we made to the Administrator in 1986 remains valid today.

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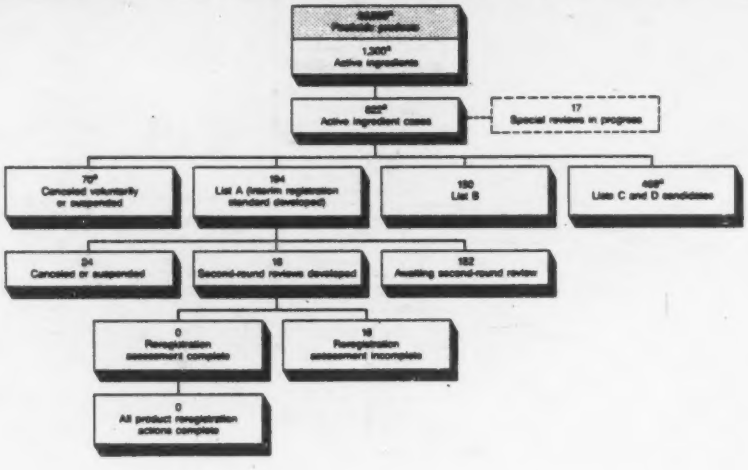
In summary, the American public has asked a lot of questions during the start of this growing season about the safety of the food they eat that is treated with pesticides, but many of the answers are unknown. Our work indicates that, despite progress, EPA is still at a preliminary stage in assessing the risks of older pesticides. FIFRA '88 will help accelerate this formidable task but does not resolve all pesticide regulatory issues. Because EPA has not been successful in meeting deadlines or implementing pesticide reforms in the past, extraordinary leadership is needed to meet the congressional mandate.

We believe that the charts we presented today will help the Congress monitor EPA's progress in reregistering pesticides and reassessing pesticide tolerances. Mr. Chairman, this concludes my prepared statement. I will be glad to respond to questions that you or members of the Subcommittee might have.

ATTACHMENT I

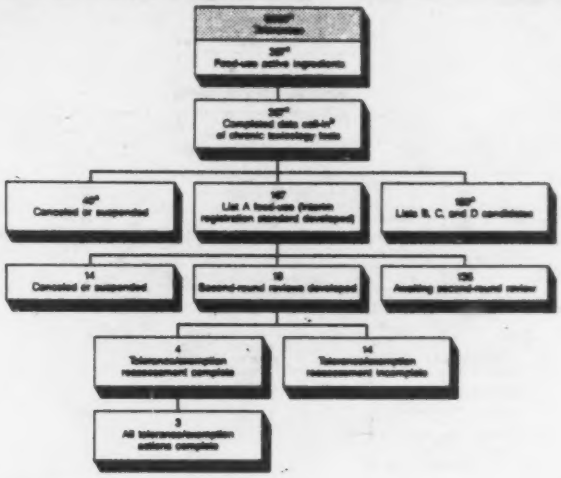
GAO Status of Pesticides Undergoing Reregistration as of April 28, 1989



[a]Number is approximate.
Source: GAO-prepared figure based on EPA information. GAO did not independently verify this information.

ATTACHMENT II

GAO Status of Tolerance Reassessment as of April 28, 1989



[a]Number is approximate.
[b]Completed Data Call-In—EPA has determined whether any chronic toxicology tests are missing and, if so, sent letters requiring registrants to submit the tests.
Source: GAO-prepared figure based on EPA information. GAO did not independently verify this information.

ESPONSES FROM GAO TO ADDITIONAL QUESTIONS FROM SENATOR REID

1. In your 1986 report on EPA's regulation of pesticides you indicated that as of March 31, 1986, EPA had not completed a final assessment of any of the 600 active ingredients which it began reviewing in 1978, as required by the 1972 FIFRA amendments.

1A. Can you tell me how many final assessments have been completed as of today?

As indicated on pages 16 and 21 of my prepared statement of May 15, 1989, EPA has not completed a final assessment on any of the approximately 822 active ingredient cases[1] now subject to reregistration. Reregistration assessment of three pesticides is essentially complete (Heliothis zea NPV, sodium and calcium hypochlorite salts, and methoprene). Because of the nature and type of these pesticides, reregistration assessment was perhaps relatively easier for EPA to do for these pesticides than for many others.

1B. Why is this process taking so long?

We concluded in 1986 that reregistration of all pesticides registered over the last four decades is a "formidable task" that would extend well into the 21st century because of the

-- magnitude of the task,

-- the lengthy and complex process under which EPA determines the acceptability of each piece of data, identifies data gaps, and makes scientific and regulatory decisions based on available data,

-- the time necessary for pesticide firms to complete health and environmental testing, which may take up to 4 years in the case of chronic toxicity tests,

-- the complexity of issues and uncertainty involved in evaluating the risks and benefits of older pesticides, and

-- EPA resource limitations which constrain, to some extent, the pace of reregistration.

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[1]EPA has combined the approximately 1,300 individual active ingredients subject to reregistration under FIFRA '88 into about 822 groups--which EPA now refers to as "cases"--containing active ingredients with similar chemical characteristics.

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1C. Will the 1988 FIFRA amendments help speed the reassessment process?

The Congress, through the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1988, significantly refocused EPA's reregistration program. FIFRA '88 imposes mandatory time frames and duties, for both EPA and registrants, for reviewing the adequacy of the data required for reregistration. In addition, EPA has been given additional funding for reassessment and about 9 years for completing the task. Thus, the amendments will help speed the process.

1D. What else, in your view, is necessary to speed this process?

As I noted in my statement, there are several unresolved issues that complicate EPA's reregistration efforts which the Congress might want to consider as it monitors EPA's implementation of FIFRA '88. First, EPA still bears the burden of obtaining a complete data base to assess the risks of most major food-use pesticides (List A). Although FIFRA '88 shifts some of the burden to the registrants to determine what is required to accomplish reregistration of any of their pesticides included on Lists B, C, and D, EPA is still responsible for determining what is required for pesticides on List A. Further, FIFRA '88 does not establish any deadlines for when EPA must have a complete data base for pesticides on List A. EPA has conducted a preliminary assessment (interim registration standard) for each of the 194 pesticides on List A. However, EPA's process for developing a complete data base needed for these pesticides is repetitive, time consuming, and labor-intensive. Further, EPA has not yet developed a schedule or plan for reregistering these important pesticides.

Second, EPA needs to improve its management information system for tracking the status of pesticides subject to reregistration. As noted in question 9 below, EPA does not have current and accurate information on the status of active ingredients, pesticide products, and tolerances subject to reregistration and reassessment. EPA needs this information to better monitor, manage and assess program progress. We believe that the two charts I presented will help EPA and the Congress monitor EPA's progress in reregistering pesticides.

Third, EPA needs to enforce label requirements imposed through registration standards. In 1986, we reported that EPA had not canceled any pesticide products for noncompliance with labeling requirements imposed by interim registration standards, although several products were not in compliance. EPA has informed us that it has not generally pursued cancellation actions for labeling noncompliance because of the cumbersome and time-consuming cancellation procedures under

FIFRA section 6. This issue needs to be addressed because label requirements are EPA's primary mechanism to regulate the use of pesticides.

2. I understand that we call the reassessments of older active ingredients "reregistration."

2A. Does EPA have a working definition of reregistration?

The simple answer to your question is no, EPA does not appear to have a working definition of reregistration. Let me first point out that while reassessment of older active ingredients is commonly called "reregistration," developing a final assessment on an active ingredient case does not complete the process of reregistration. EPA has to apply decisions reached on each active ingredient to all individual products containing that ingredient, including products that contain multiple active ingredients, and take appropriate reregistration action on each product. EPA's plan for implementing FIFRA '88 does not specify how EPA will reregister pesticide products after it completes a final assessment of an active ingredient case. EPA has invited public comments on how this shall be achieved. Until this issue is resolved, it is unclear when reregistration will have been achieved and whether the requirements of FIFRA '88 have been met.

According to EPA officials, they have reregistered some pesticide products, but the number reregistered was not available at the time we updated our report at your request.

I would also like to point out that what is complicating the issue is the need to identify a point of program closure on reregistration while still recognizing that EPA's pesticide regulatory assessments will never be "final" per se. EPA needs to keep its "final" regulatory assessments of pesticides current because of the dynamic nature of pesticide regulation. EPA's FIFRA '88 implementation plan does not specify how this will be accomplished. Keeping final regulatory assessments current will be a critical cost of doing business if EPA is to avoid costly and long-term efforts to periodically reregister pesticide products to bring them into compliance with evolving requirements, science, and uses.

2B. Has EPA established a timetable or deadlines for the reregistration of all major food-use chemicals?

As noted in my answer to question 1D. above, EPA has not yet established a timetable or deadlines for obtaining complete data bases needed to reregister all products containing most major food-use pesticides.

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2C. Without a deadline when can we expect all food-use pesticides to be reregistered?

Presumably, EPA plans to reregister all food-use pesticides within the next 9 years. Without a deadline or timetable it is uncertain when EPA will complete this task. However, EPA should establish a timetable for expeditiously reregistering all food-use pesticides to reduce the uncertainty surrounding the risks of pesticides that leave residues on the food we eat.

3A. What is the "special review" process?

The special review process is an informal EPA review process to evaluate the risks and benefits of pesticides of concern and determine whether regulatory action, such as canceling, suspending, or restricting a pesticide use, is needed. A pesticide must meet or exceed one or more risk criteria, also known as risk triggers, before EPA puts it into special review. These risk triggers include those for oncogenicity (tumor formation), mutagenicity (heritable genetic effects), and other chronic (long-term) toxic effects; acute (immediate) hazards to humans and animals; and hazards to endangered species and other wildlife. Older pesticides in special review are also subject to reregistration. More detailed information on special reviews is contained in chapter 7 of our 1986 report.[2]

3B. How many special reviews has EPA initiated since the program's inception in 1975?

In 1986, we reported that EPA had initiated special reviews for 51 pesticides as of October 1985. We do not have more recent information. However, EPA may be able to provide this data.

3C. My understanding is that the special review is designed to deal more quickly with pesticides suspected of posing significant health risks. Your 1986 report stated that the special review process took two to six years. Why does it take so long?

We reported in 1986 that the special review program had been criticized for taking too long to complete reviews of pesticides. Special reviews completed through October 1985 had generally taken 2 to 6 years or longer to complete. According to EPA officials and records, a number of factors

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[2]PESTICIDES: EPA's Formidable Task to Assess and Regulate Their Risks (GAO/RCED-86-125, April 18, 1986).

contributed to the length of time it took EPA to complete special reviews. These factors included:

-- the complexity of issues and uncertainty in risk and benefits data;

-- delays in getting needed studies and data, or studies having to be redone;

-- limited resources--other pesticide program work competed for review time; and

-- receipt of additional, unexpected data that must be reviewed and that may alter risk or benefit calculations, requiring EPA to consider different regulatory options.

3D. Has there been any improvement since 1986?

In 1986 we reported that EPA was taking action to speed up the special review process in several ways. First, EPA was issuing data call-in letters to pesticide registrants to more quickly obtain data needed for decision-making. Second, EPA anticipated that integrating the registration standard and special review processes would enable EPA to complete special reviews more quickly because interim registration standard development would identify any and all risk concerns and generate much of the data that would be needed for a special review. Third, EPA proposed to improve the efficiency of the special review process by changing the criteria and procedures relating to special reviews. The new criteria provided for consideration of exposure as well as toxicological effects of a pesticide. Because of the recency of these actions at the time we issued our report, we were unable to determine the effectiveness of these actions.

Although we have not evaluated EPA's special review program since we issued our report in 1986, we would like to note that a major impediment to the identification and evaluation of pesticides of concern in special review is the lack of data available on pesticides. Consequently, the pace of special reviews is, to a large extent, constrained by the pace of EPA's efforts to obtain and review data on older pesticides in its reregistration program.

3E. How can we speed up the process?

Although FIFRA '88 will help accelerate the production of data needed to assess the risks and benefits of older pesticides, it does not specifically speed up EPA's special review process. The fees provided under FIFRA '88 will help offset the costs of accelerating reregistration. However, according to the head of EPA's FIFRA '88 implementation task force, the

fees will probably not cover the cost of an increased or an accelerated special review program. EPA expects its future special review workload will be substantial as special review pesticides are identified during reregistration.

In 1986 we offered two possible alternatives for the Congress to consider to accelerate the special review process:

-- Providing EPA with additional resources to allow it to more quickly review studies and data related to on-going special reviews, and to meet future increases in the special review workload anticipated by EPA.

-- Setting deadlines for completion of special reviews (or for some or all of the special review phases) which recognize the complexities of special review, and the resource requirements necessary to meet such deadlines.

4. If EPA takes six years to finish the special review and then decides to cancel the pesticide, how long can the cancellation process take?

If EPA proposes to cancel a pesticide following a special review, the affected registrants are entitled, under FIFRA, to a full adjudicatory hearing on the merits of EPA's decision to cancel the registrations. These hearings provide an opportunity for the registrant to rebut EPA's decision. Although we have not specifically evaluated the cancellation procedures provided under FIFRA, we reported in 1986 that this administrative hearing process can take 2 or more years to complete. Further, it is an extremely resource-intensive undertaking in which the substantive risk/benefit issues decided upon in the special review process may be reexamined intensively through expert testimony and cross-examination. EPA officials would like to streamline the existing cancellation process by establishing rule-making as the primary method for determining whether products cause unreasonable adverse effects on health and the environment and what regulatory steps should be taken to address such effects. EPA officials believe that this proposal would require legislative change and have testified on this matter before several congressional committees. More information on this idea is contained in chapter 7 of our 1986 report.

5. In your 1986 report you stated that EPA needed to reassess tolerances for 390 older pesticides to determine whether these levels present health hazards.

5A. Why do these tolerance levels need to be reassessed?

Many existing tolerances were established previously without all the data EPA now requires to assess health risks of

food-use pesticides according to current scientific standards. Many tolerances were established without adequate chronic toxicology and/or residue chemistry data. For example, EPA is missing chronic toxicology and residue chemistry data needed to reassess the safety of food residues of ethoprop, an insecticide used extensively on field corn. Although EPA issued a "second-round review" for ethoprop in June 1988, it will be at least 4 years before the required tests are submitted and tolerances reassessed by EPA. In the meantime, ethoprop can continue to be used.

5B. How many of these tolerance levels have been reassessed?

As noted in my prepared statement on pages 17 and 22, EPA has completed tolerance reassessment for only four pesticides (Heliothis zea NPV, methoprene, sodium and calcium hypochlorite salts, and fosetyl-Al (Aliette)). I would like to point out that these four pesticides either have few food uses or were exempt from most data requirements because of their relatively low toxicity. Further, one of the four is no longer being produced, according to the EPA product manager. Thus, tolerance reassessment for these four pesticides was relatively easy to do and probably not representative of the vast majority of food-use pesticides for which tolerance reassessment is incomplete.

It is also important to recognize that tolerance reassessment for a pesticide does not complete the process of bringing older tolerances and tolerance exemptions into compliance with current EPA requirements. Once EPA completely reassesses tolerances for an older pesticide it must implement its regulatory decisions, such as changing or revoking existing tolerances or establishing new tolerances. Implementing these decisions requires time and resources. EPA has completely implemented all tolerance actions for 3 of the 4 pesticides for which tolerance reassessment is complete, as illustrated in attachment II of my prepared statement.

5C. Is there a timetable for reassessing these tolerances?

As noted in my answer to question 1D. above, EPA has not yet established a timetable or deadlines for obtaining complete data bases needed to reregister all products containing most major food-use pesticides. This also means that EPA has not yet established a timetable for reassessing tolerances associated with these pesticides.

5D. In the meantime can we guarantee the public that the pesticides allowed on food are safe and the public's exposure is of no concern?

The health risks related to pesticide residues in food are uncertain because for many pesticides with previously established tolerances, EPA lacks the data needed to determine safe residue limits. Obviously, expeditiously reassessing tolerances and reregistering older pesticides would greatly reduce the uncertainty of the risks and help restore public confidence in the safety of the U.S. food supply.

5E. How assuring is it to you, personally, when the companies announce that the residues on food are below the residue tolerance levels?

It is encouraging that food processors, retail stores, and pesticide manufacturers have recently undertaken more testing for pesticide residues. Testing by industry can supplement government efforts and help make growers aware of public concern over pesticide residues.

On the other hand, industry testing is not independently verified, and methodological information is not always disclosed. Therefore, consumers do not have a means to judge the adequacy and objectivity of such testing. For instance, if industry were to provide information on their sampling and analytical methods, consumers could better judge how meaningful test results are.

For a few pesticides, manufacturers have done monitoring studies for EPA to use in assessing exposure to pesticide residues. EPA has reviewed the methodology of these studies. However, as we pointed out in recent testimony,[3] EPA presently has no guidelines for monitoring studies. EPA began work to develop guidelines for monitoring studies and several other types of residue studies in March 1989. In our testimony, we recommended that EPA establish such guidelines as soon as possible.

6A. In reassessing tolerances, what food consumption data does EPA rely on?

EPA currently uses food consumption data based on a 1977-78 USDA nationwide survey. This survey sampled over 30,000 people and asked what foods and beverages they consumed over a

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[3]Guidelines Needed for EPA's Tolerance Assessments of Pesticide Residues in Food, (GAO/T-RCED-89-35, May 17, 1989).

3-day period. This food consumption data is in EPA's automated Tolerance Assessment System (TAS). Because most tolerances are set for raw agricultural commodities, TAS list food consumption in terms of raw commodities. If a survey respondent reported eating apple pie, for example, TAS recipe files are used to calculate the amount of apples, sugar, flour, etc., consumed. TAS groups survey respondents into 22 population subgroups, based on age, gender, race, region of residence, and season of the year in which surveyed. TAS provides exposure estimates for the overall U.S. population (including all subgroups), as well as for each subgroup.

EPA plans to update TAS with results of the 1987-88 USDA nationwide survey of food consumption. The 1987-88 survey sampled less than half the number of people sampled in the prior nationwide survey. USDA has completed administering questionnaires for the 1987-88 survey and is currently compiling the data. After survey results are compiled, we plan to evaluate to what extent the smaller sample size affects the precision of the subgroup data used in TAS. We also plan to evaluate whether EPA could use other USDA food consumption surveys, such as the 1986-87 survey of food consumption among children 1 to 5 years old and their mothers, in combination with the nationwide survey, in order to provide larger numbers for TAS subgroups.

6B. For the older pesticides we spoke of earlier, for instance the fungicides, what kind of diet was the basis for calculating residue tolerance levels?

Prior to implementing TAS in 1986, EPA used the "food factor" method to estimate exposure to pesticide residues in food. The food factor method provided an exposure estimate for the U.S. population; information on population subgroups' exposure was not available. The food factor method based average food consumption figures and body weight on young adult males. It used the 1965 USDA nationwide survey as the basis of food consumption estimates.

While older pesticides would probably have been initially evaluated using the food factor method, more recent actions for these pesticides may have used TAS exposure estimates. For instance, if a pesticide manufacturer applied for a new tolerance for one of these older pesticides within the past year, EPA would have used TAS to generate exposure estimates.

6C. In the process of reassessing tolerances, is EPA required to take into account the special susceptibility of infants and children?

Current pesticide laws (FIFRA and FFDCA) do not require EPA to take the special susceptibility of infants and children into account. Nor do EPA regulations require it.

The special susceptibility of infants and children is one of the topics to be addressed in a study the National Academy of Sciences is performing for EPA. This study of the scientific and regulatory issues concerning pesticides in the diets of infants and children is expected to be completed in the Fall of 1990.

6D. Does EPA take account of the fact that infants and children consume more fruits and vegetables for their size and body weight than adults?

EPA uses TAS to generate exposure estimates for population subgroups, including nursing and nonnursing infants, children 1 to 6 years old, children 7 to 12 years old, males 13 to 19 years old, and females 13 to 19 years old. These exposure estimates are based on food consumption reported for the individuals surveyed in these subgroups. TAS expresses exposure as milligrams of a pesticide's residue per kilogram body weight per day. Therefore, TAS exposure estimates reflect exposure in relation to the body weights of those surveyed.

While EPA has information available concerning infants' and children's food consumption and exposure, it does not have a policy as to whether, and/or in what circumstances, tolerance decisions are to be based on the subgroup which is most highly exposed. Infants and young children most often have the highest exposure estimates because they consume more food in relation to their body weight than do adults. However, specific information on population subgroups' cancer risk is not generally available to EPA officials responsible for making decisions about tolerance proposals and reassessments of existing tolerances. Instead, cancer risk estimates for the overall U.S. population, which reflect exposure and food consumption patterns from infancy through adulthood, have been provided to decision makers. EPA does, however, separately consider subgroup data on a regular basis when it assesses other health risks such as reproductive system damage.

In our recent testimony on this issue, we recommended that EPA calculate and consider cancer risk for the most highly exposed

subgroup.[4] We also recommended that EPA proceed now to establish a policy concerning whether, and/or in what circumstances, tolerance decisions are to be based on the most highly exposed subgroup(s).

7A. Will EPA meet the deadlines as set forth in the 1988 amendments to FIFRA?

It is too soon to tell whether EPA will meet the deadlines as set forth in FIFRA '88. A lot can happen in 9 years. EPA has met the deadlines so far. However, if the "past is prologue," then the odds do not look good for EPA because it has not been successful in meeting deadlines or implementing pesticide reforms in the past.

As noted above, we are concerned about a number of management issues that could jeopardize the success of EPA's reregistration efforts. In particular, EPA needs to address the unresolved issues that I discussed in questions 1D, 2A and 2C.

7B. What does EPA need to do in order to meet the 1988 FIFRA deadlines?

In our 1988 transition series report on EPA issues, we concluded that extraordinary leadership is needed to meet the new congressional mandates.[5] Further, we concluded that to effectively implement the accelerated assessment program, EPA needs to, among other actions,

-- concentrate on meeting each deadline in the act as it comes due rather than the final 9-year deadline (once intermediate deadlines are missed, it will be nearly impossible to make up the lost time, given prior agency performance);

-- hire and train high-caliber staff to review the volume of industry-submitted health and environmental studies that will be needed to make regulatory decisions on each pesticide ingredient; and

-- establish quality controls to ensure that industry-submitted studies are reliable, valid, and complete and

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[4]Guidelines Needed for EPA's Tolerance Assessments of Pesticide Residues in Food (GAO/T-RCED-89-35, May 17, 1989).

[5]Environmental Protection Agency Issues (GAO/RCED-89-20TR, Nov. 1988).

audits and scientific reviews and assessments of the studies are independent, thorough, and accurate.

8. For the food-use chemicals that now need to be reregistered who has the burden to determine where the data gaps lie?

As noted above, EPA continues to bear the burden of identifying missing and inadequate data for the 194 pesticides on List A, which represents most of the major food-use pesticides. We determined in 1986 that this burden is a time-consuming and labor-intensive reregistration approach for EPA.

9. Does EPA have an adequate management information system for tracking its review of pesticides?

We have not evaluated EPA's management information systems for tracking its review of pesticides. However, it is apparent that EPA's information system for tracking the status of pesticides subject to reregistration is deficient. EPA does not have current and accurate information on the status of active ingredients, pesticide products, and tolerances subject to reregistration and reassessment. For example, in updating our report in preparation for your May 15, 1989 hearing, EPA could not tell us how many pesticides had been canceled voluntarily or suspended as a result of its reregistration efforts with any degree of certainty. EPA's planned inventory of the List A pesticides confirms the fact that EPA has not fully come to terms with developing a sound management information system for tracking the status of pesticides undergoing reregistration and tolerance reassessment.

We developed the two charts I presented during my testimony mostly from information provided by EPA and analysis of the 18 second-round reviews that EPA had completed at that time. We noted in the charts that some of the numbers were approximate because they represented only EPA's "best guess."

We believe that these two charts will help the Congress monitor EPA's implementation of FIFRA '88. The Congress may want EPA to update the charts periodically by filing in the boxes and providing detailed lists of pesticides to support each box.

I would like to underscore this point with one observation. We are concerned with the reliability, accuracy, and completeness of the information EPA has provided to us and others concerning its reregistration efforts. EPA cannot fully support the information it provides on the status of pesticides undergoing reregistration and continually changes what information it does provide. Deficient information on the status of pesticides undergoing reregistration threatens

to undermine the credibility and accountability of this program.

10A. We have heard that many studies are overdue and that EPA leaves studies that are submitted unreviewed for months, is this true?

In 1986 we reported that EPA was just beginning to deal with the administrative and legal issues involved in following up on--monitoring and enforcing--interim registration standard requirements. The rate of registrants' compliance with reregistration requirements has improved since we issued our report, but is still troubling. In 1986, about 50 percent of registrant responses to reregistration requirements were overdue. As of April of this year, about 33 percent of registrants' responses were overdue. Because registrants may respond in more than one way to reregistration requirements, overdue responses do not necessarily equate to overdue studies. Registrants may respond in several ways to requirements, such as withdrawing product registrations, amending registered product uses to eliminate the need to do a study, or submitting a study. Further, the requirements range from simple 90-day studies to 4 year chronic toxicity studies.

We have not performed further follow-up work to determine the number of studies that are overdue. Further, we have not determined EPA's backlog of study reviews. However, we did report in 1986 that EPA expected that it would be unable to review immediately upon receipt all the new studies registrants would submit in response to reregistration requirements. This may still be a concern under the accelerated FIFRA '88 reregistration program.

10B. How many studies are overdue?

In addition to my answer to question 10A., I suspect that EPA does not know how many studies are overdue at this time because it plans to conduct an inventory of the List A pesticides, in part, to determine which studies are overdue.

10C. How many chemicals have completed all studies but EPA hasn't reviewed them yet?

As noted on page 15 of my prepared statement and in question 10B above, EPA plans to conduct an inventory of the data available for each List A pesticide for which a second-round review has not been completed. Until EPA completes this inventory, expected this summer, this question cannot be fully answered.

In March, 1989, EPA informed the Chairman, Environment, Energy, and Natural Resources Subcommittee, House Committee on

Government Operations, that 37 pesticides had sufficient data available for second-round review. Presumably, when EPA schedules a second-round review, it has received all the data needed to assess a pesticide. However, EPA's experience to date shows that second-round reviews are only another iteration in EPA's lengthy and time-consuming process of identifying missing and inadequate data and requesting data from registrants for the List A pesticides. Our review of the 18 second-round reviews that EPA had completed through April, 1989, shows that EPA lacked sufficient data to completely assess the risks associated with most of these 18 pesticides.

THE MOUNT SINAI MEDICAL CENTER
ONE GUSTAVE L. LEVY PLACE • NEW YORK, NY 10029-6574

Mount Sinai School of Medicine • The Mount Sinai Hospital

Department of Community Medicine
Division of Environmental
and Occupational Medicine
Box 1057/1058

(212) 241-6173

Testimony of

Steven B. Markowitz, M.D.
Deputy Director, Division of Environmental and Occupational Medicine
Assistant Professor of Community Medicine
Mount Sinai School of Medicine
1 Gustave L. Levy Place
New York, N.Y. 10029

Before the
Subcommittee on Toxic Substances, Environmental Oversight, Research and Development
United States Committee on Senate Environment and Public Works
Washington, D.C.

Monday, May 15, 1989

My name is Steven Markowitz, M.D. I am Deputy Director of the Division of Environmental and Occupational Medicine and an Assistant Professor in the Department of Community Medicine at the Mt. Sinai School of Medicine in New York City. I am a physician specializing in occupational and environmental medicine. A significant part of my research and clinical activities at Mt. Sinai involves the assessment of the human health effects of exposure to pesticides. In addition, I served as a peer reviewer for the recent study on pesticides completed by the Natural Resources Defense Council.

Pesticides are unique among commercial chemical substances in that they are deliberately toxic. The safe use of these inherently lethal agents depends upon a number of factors. One of these factors is the differential susceptibility of humans versus insects, fungi, and other pests to the effects of these agents. A second factor crucial to the safe use of pesticides is the effective segregation of humans from exposure to pesticides targetted for unwanted pests. Such segregation requires a complex and difficult system of controls in order to limit human exposure to pesticides. Today I wish to comment on why I believe that the current system of controls is not maximally effective.

First, it is important to recognize that we are largely ignorant of the human health effects produced by exposure to the 600 or more pesticides currently in use. A review of this topic by the Natural Research Council in 1984 concluded that a complete health hazard assessment is currently available.for only ten percent of pesticides and the inert ingredients which accompany pesticides. Furthermore, for two-thirds of these pesticides and their inert partners, either no or minimal toxicity information is currently available. The EPA has similarly found a massive absence of data in its

attempt to evaluate the safety of pesticides over the past decade. Therefore, whatever we currently claim to know about the potential human health problems associated with pesticide exposure is clearly dwarfed by our ignorance about substances to which we may have daily exposure.

One of the few areas of pesticide toxicology in which we do have limited knowledge is the impact of selected pesticides on the human nervous system. While much attention has appropriately been focused on the cancer-causing properties of pesticides, it would be unwise to slight the human nervous system as an important target organ for the action of pesticides absorbed into the human body. The nervous system forms an especially important site of pesticide toxicity due to its complexity, its very limited ability to recover from toxic insults, and its obvious role in the control of many crucial functions, mental and otherwise, of the human body.

Organophosphate and carbamate pesticides are among the most commonly used groups of pesticides in the United States and have been shown to cause at least two distinctive neurologic syndromes in humans. Organophosphates and carbamates are acutely toxic, producing irritability, anxiety, muscle twitching, widespread automonic nervous dysfunction, seizures, coma, and death. All members of the classes of organophosphate and carbamate pesticides are toxicologically similar in that they have a common mode of action in disrupting the nervous system. These pesticides have served as the principal replacements for DDT and its relatives, which have been banned or highly restricted over the past 20 years. Paradoxically, due to their high acute toxicity, these newer classes of pesticides, the organophosphates and carbamates, have probably caused more immediate deaths than their hazardous predecessors.

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A second neurologic syndrome related to the organophosphate pesticides is that of a delayed peripheral neuropathy. Selected members of this pesticide class can produce not only the immediate neurological symptoms cited before, but can also cause crippling long-term damage to the nerves of the arms and legs of exposed individuals resulting in muscular weakness, incoordination, and numbness. These symptoms begin several weeks after last exposure. Most of these neurologic effects have occurred after clear circumstances of over-exposure to the pesticides of concern.

Aside from these two specific neurologic effects, there is a growing body of evidence that low-level chronic exposure to pesticides can produce neurologic symptoms, particularly neuropsychological deficits, including problems with memory, attention, concentration and other cognitive processes. This is an area of increasing concern and research given the curent widespread low-level exposure to pesticides.

These neurotoxic effects of pesticides are especially alarming in view of the current exposure of children to organophosphates and carbamates. The human nervous system is immature at birth and requires years for full development. During these years of development, children are particularly susceptible to the effects of neurotoxins. The scientific literature documenting the effects of pesticides on the developing nervous system in children is slim, but studies of animals demonstrate a clear age-related sensitivity to the effects of pesticides. The neurotoxic organophosphates in particular are lethal to young animals at much lower doses then those producing death in adult animals. Even at doses which are not lethal, young animals show clear and identifiable destruction of the nervous system at doses much lower then those given to adult animals of the same species.

In view of these findings, the recent study completed by the Natural Resources Defense Council raises some important and disturbing questions.. The authors combined data concerning age-specific food consumption patterns and actual measurements of pesticide residues found in fruit and vegetables. These data were obtained from the Environmental Protection Agency and the Food and Drug Administration. The authors examined total organophosphate exposure by converting the exposure to fourteen individual organophosphates to a common unit. This is reasonable given the common mode of action of the organophosphates.

The NRDC scientists concluded from their analysis that between three and ten million pre-school children receive exposure on a daily basis to neurotoxic organophosphate pesticides contaminating raw fruits and vegetables at a level above that considered acceptable by the Environmental Protection Agency. Indeed, if one examines both raw and processed fruits and vegetables consumed by pre-school children, then virtually all pre-schoolers have a daily exposure to these pesticides above the level considered acceptable by the Environmental Protection Agency.

A question naturally arises: Are these children ill? Frankly, we do not know. Studies of the neurodevelopment of children are exceedingly difficult due to a number of factors, including the great variability in behavioral development among children, the large number of variables that can influence development, the difficulty of measuring the absorbed dose of pesticides, and the complexity of the many endpoints of neurologic concern. Furthermore, it is reasonable to assume that it will be many years before the neurotoxic effects of relatively low-level pesticide exposure to school children will be amply studied, and, therefore, I believe that we need to rely on currently available limited data to guide us in formulating present public policy.

The example of another well-known childhood neurotoxin can, perhaps, be illustrative. In the 1960's, when childhood lead poisoning became an issue of broad public concern, the principal public health focus was on preventing overt clinical lead poisoning, chiefly, the brain swelling, caused by lead exposure, and an acceptable limit of lead in the blood was set at 50 micrograms per deciliter of blood (ug percent). In the intervening two decades, as more sophisticated studies have been completed, the level of blood lead considered acceptable has been lowered several times, presently down to 25 ug percent. This change in the tolerated blood lead level has occurred in response to an increasing appreciation that low levels of blood lead are associated with a wide range of neuropsychological deficits. Recent alarming studies have shown that blood lead levels in the range of 10 to 15 ug percent during the prenatal period can cause alterations in the neurological development of children for at least several years after birth. These are disturbing findings, since blood lead levels of 10-15 ug percent were routinely found among urban pregnant women as little as 15-20 years ago, prior to the reduction in the use of lead in gasoline. In summary, as the scientific method for assessing the damage to the nervous system by an environmental toxin such as lead has improved, we have realized that previously accepted levels of exposure have been shown to be deleterious and that a ubiquitious neurotoxin can present a widespread and important detriment to the healthy development of children.

What do we do with this knowledge? Setting aside the problem of cancer caused by current levels of exposure to pesticides, the following factors --- the known human neurotoxicity of pesticides, the age-related susceptibility associated with pesticide exposure, and the exposure estimates obtained from EPA and FDA data by the Natural Resources Defense Council study, --- these factors all point to the need for a significant reduction in exposure to pesticides. Our present knowledge, is not perfect but it is sufficient in order to take the necessary steps to protect public health. Several concrete steps are possible. First, all pesticides should be thoroughly tested specifically for

neurotoxic effects prior to marketing. This pre-marketing testing should include assessment of the chronic neurologic effects of low level exposure to pesticides: this is not currently performed. Second, the pesticide residue monitoring program should be expanded, so that all pesticides of potential importance are monitored. Third, the setting of tolerance levels for individual pesticides should not assume that children are exposed to only one pesticide from only one food item, but should account for the totality of pesticide absorption from the mixture of raw and processed fruit and vegetables that we encourage our children to eat.

In conclusion, despite decades of effort and experience in the area of pesticide regulation, a fully effective system of controls to limit human exposure to pesticides has not yet evolved. The recent public response to the Natural Resources Defense Council study and the persistent high level of concern demonstrated by the American people over pesticide residues in food provides Congress with a mandate to make needed changes in the current system of pesticide regulation.

I thank you for your attention and will be glad to answer any questions.

Advancing psychology as a science, a profession, and as a means of promoting human welfare

TESTIMONY OF

Ronald W. Wood, Ph.D.

Research Associate Professor of Environmental Medicine

New York University Medical Center

on behalf of the

AMERICAN PSYCHOLOGICAL ASSOCIATION

before the

UNITED STATES SENATE

Subcommittee on Toxic Substances, Environmental Oversight

and Research & Development

Committee on Environment & Public Works

on the subject of

Chemicals and Food Crops

May 15, 1980

The Honorable Harry Reid, Chairman
406 Dirksen Senate Office Building

1200 Seventeenth Street, N.W.
Washington, D.C. 20036
(202) 955-7600

Chemicals and Food Crops
Subcommittee and Toxic Substances
May 15, 1989

Statement Summary

Findings:

- o Children are especially vulnerable to a variety of toxic materials found in food and in the environment. This vulnerability is due to their achieving higher concentrations of chemicals in vulnerable organs, and to interference with normal processes during development.

- o Involuntary chronic exposure to chemicals that result in effects on behavior or the nervous system are of great concern, particularly with regard to insecticides designed to kill by adverse effects on the nervous system of the pest. Workers using pesticides bear the greatest risk of injury.

- o The hazards to the psychological and neurological development of children from ingesting pesticide residues on food or in drinking water are unknown. This results from grossly inadequate testing of pesticides for neurotoxicity. Those charged with protecting the nation's food supply and drinking water must have the information necessary to do their job and to maintain public trust.

- o The National Academy of Sciences recommends that children and adults should eat a healthy diet including a wide variety of fruits and vegetables. In light of the public health benefits that accrue from an affordable healthy diet, the risk to health from consuming pesticide residues of food additives must be considered.

Recommendations:

- o Testing of pesticides and their inert ingredients for neurobehavioral toxicity should be required during the registration and reregistration process. EPA needs more staff with expertise in neurobehavioral toxicity evaluation in the Office of Pesticides.

- o Since EPA has limited experience in establishing testing guidelines for neurotoxicity evaluation of pesticides other than organophosphates, improved surveillance of the health of workers involved in manufacturing, mixing and applying these chemicals should be undertaken. Workers serve as a sentinel for the health of the rest of the nation; NIOSH and other agencies should be provided with resources adequate for this task.

- o Attempts should be made to identify toxins that will be missed by those testing procedures that EPA eventually decides to adopt. Their selected

tests should be incorporated in more intensive chemical toxicity testing programs conducted by EPA, the National Toxicology Program, and the regulated industry.

- Expanded research programs should be undertaken to detect and characterize subtle or unrecognized forms of behavioral and neurological impairment produced by brief and longterm exposure to representative pesticides throughout the lifespan. These programs should focus on impairment of sensation and perception, on disorders of cognition (e.g. learning and memory), emotional well-being, and on motor skills and coordination. The intra- and extramural programs of EPA, FDA, NIEHS, and NIOSH should be expanded or refocused to accomodate these efforts.

Chemicals and Food Crops
Subcommittee and Toxic Substances
May 15, 1989

Mr. Chairman, thank you for the opportunity to testify concerning the neurobehavioral toxicity of chemicals used on food crops. I am Dr. Ronald W. Wood, Research Associate Professor of Environmental Medicine at the New York University Medical Center. I am here today on behalf of the American Psychological Association's 90,000 members, including psychologists with interests in various aspects of normal and abnormal psychological functioning. I am a psychologist interested in the neurobehavioral toxicity of chemicals, especially those which are present in the workplace and in the environment.

I am also chairman of the APA Committee on Neurobehavioral Toxicity Test Standards of the Division of Psychopharmacology; this committee has been following with interest EPA's attempts to cope with the neurobehavioral toxicity of chemicals regulated under the Toxic Substances Control Act (TSCA), and, more recently, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). A member of our committee, Dr. Robert L. Balster of the Medical College of Virginia, recently appeared before this committee on the subject of toxic materials in the aerospace industry. We have been asked today to comment on the neurobehavioral consequences of dietary pesticide exposure of children, and on the current state of neurotoxicity testing for pesticides and other chemicals. In the process of doing so, we have examined the report of the Natural Resources Defense Council, "Intolerable Risk: Pesticides in our Children's Food", and some of the literature referred to therein. We share with NRDC a concern about the potential risks to public health of pesticide exposure, we appreciate their calling attention to this issue, and we support some of their findings and recommendations.

In this testimony, I will:

- o Identify those portions of the NRDC report with which we are in strong agreement.
- o Discuss organophosphate exposure and its significance.
- o Challenge the adequacy of current procedures for setting Allowable Daily Intakes (ADIs) of food, which are used to set standards relative to pesticide ingestion, based on a no-observed-effect level (NOEL).
- o Offer a few remarks on the balancing of risks and benefits of pesticide use.

o We have also attached an appendix which includes additional information for the committee's benefit.

Areas of Strong Agreement with the NRDC Report

"...The problems posed by pesticides cannot be solved overnight. Effective federal government programs that protect humans and the environment are essential..." (p.27)

"...groundwater, the source of drinking water for half the nation, can be a significant additional source of pesticide exposure..." (p.96)

"...the full extent of the neurotoxic risk from organophosphate exposure is unknown since the government does not require comprehensive testing for neurotoxic effects of these pesticides. Currently, the only mandatory test assesses solely the potential for causing specific delayed paralytic reaction following acute and subacute exposure. Nonetheless, studies suggest that low-level, chronic exposure to organophosphates can cause behavioral impairments and may alter neurological function...the full extent of the impact on preschooler health from exposure to pesticides in food is unknown since the majority of pesticides in current use have not been tested according to modern testing requirements..." (pp.96-97).

"...age-related susceptibility has been documented for a number of neurotoxins..." [many examples] (pp.125-126)

"...Sensitivity of the young results from physical immaturities in the nervous system such as incomplete blood brain barrier, nerve fiber coverings and receptor development..." [discussion] "...(these studies) do indicate that exposure to some organophosphates and carbamates early in neurological development may alter neurological function and may cause subtle and long lasting neurobehavioral impairments..." (pp.127-133).

"...The full extent of the preschool health impact from exposure to pesticides in food is unknown since data on the health effects of many pesticides are lacking..." (pp.148-151)

"...EPA has systematically failed to consider the health and environmental effects of 'inert' ingredients in regulating pesticides..." (p160).

"...EPA does not require any evaluation of effects of exposure on such processes as learning ability, activity level and memory, or on sight, hearing, emotion and other expressions of neurobehavioral activity. This is

the case despite recommendations for comprehensive neurobehavioral testing of pesticides..." (pp.160-162).

"...EPA must require systematic testing of all pesticides for their potential to cause neurological damage..." (pp.177-178) [We would permit exceptions only for those rare circumstances under which no human exposure can occur]

My support for the above findings of the NRDC report is based on a comprehensive review of the existing scientific literature on this subject as well as discussions with researchers in the public and private sector. The materials that have been provided at the end of my statement help to bring into perspective the striking paucity of test data on pesticides and other toxic substances. A 1984 National Academy of Sciences report entitled "Toxicity Testing: Strategies to Determine Needs and Priorities" highlighted the extent to which the toxicity of existing and new chemicals is unknown. The study found that only 34 percent of the pesticides reviewed have been tested adequately enough to conduct a partial assessment of their potential hazard to human health. Even more disturbing is that for 38 percent of pesticides and their inert ingredients no toxicity data at all are available. The NAS concluded that "it is clear that thousands or even tens of thousands of chemicals are legitimate candidates for toxicity testing related to a variety of health effects..." and that neurobehavioral toxicity evaluation is one of the highest priority toxicity testing needs. Little has changed in this regard since the release of this study in 1984.

The NRDC Estimate of Organophosphate Exposure and its Significance

The NRDC report is based on a methodology for calculating the ingestion of pesticide residue and a diet survey that differs from that which is typically employed by EPA. The crux of their argument is that the EPA diet surveys do not reflect current eating patterns of children, and that exceeding the Allowable Daily Intake (ADI) as set by EPA represents a threat to health. EPA calculates an ADI by determining a no-observed-effect level (NOEL) from an animal study and applies a safety factor of 100 or more to that value; in the case of organophosphate pesticides, this is usually done on a measure of acetylcholinesterase (ACHE) inhibition, i.e. the impairment of the enzyme which breaks down acetylcholine (a neurotransmitter). Thus a safety factor is applied to a dose from which no detectable inhibition occurs.

Impairing the cholinesterase enzyme results in overstimulation of the nervous system that can result in adverse effects leading to death. Some chemical warfare agents work in this manner. However, the significance of

low level cholinesterase inhibition is not completely understood. Many assume that 50% ACHE inhibition is required before overt functional effects occur; thus at lower levels of inhibition, percent inhibition might reasonably be thought of as an index of exposure rather than an index of functional impairment. Cholinesterase inhibition is poorly correlated with functional indices of neurotoxicity; there may be persistent inhibition of cholinesterase in the absence of obvious signs of impairment. Tolerance may develop to the obvious effects of cholinesterase inhibitors.

On the other hand, recent reports suggest that there may be learning impairment in animals otherwise fully tolerant to obvious signs of ACHE inhibition. We do not know the full consequences of chronic cholinesterase inhibition for the other systems of brain chemistry that may be indirectly affected by changes in cholinergic transmission. The consequences of chronic low level ACHE inhibition are not well understood at any age, but they are clearly of concern, and warrant further investigation.

Are Current ADIs Based on Appropriate Information?

In the case of organophosphate pesticides, cholinesterase inhibition does not predict the specific neuropathy produced by some of these pesticides; the agency has two testing methods to identify this potential injury. However, organophosphates are just one type of insecticide, and others produce no change in cholinesterase; yet the same regulatory procedures apply to the other pesticides regulated by this office, including fungicides and herbicides. At this time, there are no other required tests for neurotoxicity other than observing the test animals in their cages and a minimal examination of the nervous system for gross injury. Such observations may detect effects at very high levels of exposure, but they are, next to death, among the least sensitive techniques available for establishing a no-effect level.

The American Psychological Association, the Center for Science in the Public Interest, and other organizations concerned about the neurotoxicity of pesticides petitioned EPA seeking the adoption of more sensitive and appropriate testing methods. The Agency has yet to require routine use of appropriate neurotoxicity testing methods, even though guidelines for such testing have been developed within the Office of Pesticides and Toxic Substances.

Despite the fact that many pesticides are designed to specifically attack the nervous system, in the absence of sensitive measurements of

nervous system integrity, the ADIs are set on the basis of (no) observed effects on the otherwise most sensitive indicators of organ system damage, biochemical changes, changes in body weight, and so forth. The Agency thus assumes that protecting against other kinds of injury will protect against neurobehavioral toxicity, undermining our trust in the current ADIs.

We recommend required testing of pesticides and their inert ingredients for neurobehavioral toxicity during the registration and reregistration process. EPA will need more staff with expertise in neurobehavioral toxicity evaluation to cope with this increased level of effort in the Office of Pesticides.

Since EPA has limited experience in establishing testing guidelines for neurotoxicity evaluation of pesticides other than organophosphates, surveillance of the health of workers involved in manufacturing, mixing and applying these chemicals should be improved. Workers deserve a safe workplace themselves, and they serve as important sentinels for the health of the rest of the nation.

We further recommend that NIOSH and EPA be provided with resources adequate for expanding surveillance of worker populations for prevention of pesticide injuries, and for the identification of new or persistent disease states when they occur.

No testing scheme is perfect. It is very likely that some neurotoxic chemicals will evade detection. It becomes a certainty that this will occur if rodents are the only test species used, since they are insensitive to some types of sensory and motor injuries. In order to improve the efficiency of these early screening techniques, attempts should be made to identify the types of toxicity that will be missed by whatever testing procedures EPA eventually adopts.

We urge that when EPA selects tests for the routine neurotoxicity screening, these tests be routinely incorporated along with other more sophisticated and intensive testing techniques in the toxicity testing programs conducted under the auspices of the National Toxicology Program, or other governmental or industrial programs.

There should be an expansion of research programs to detect and characterize subtle or unrecognized forms of behavioral and neurological impairment produced by short-term and long-term exposure to representative pesticides throughout the lifespan of exposed populations. These programs should focus on impairment of sensation and perception, on disorders of cognition (e.g. learning and memory), emotional well-being, on motor skills and coordination, and changes in the structure and function of the nervous

system. The intra- and extramural programs of EPA, FDA, NIEHS, and NIOSH should be expanded or refocussed to accomodate these efforts.

Balancing the Benefits Against the Risks of Pesticides

The National Academy of Sciences has recommended that people eat 5 or more servings of fresh fruits and vegetables every day. The interests of public health are not served to the extent that people refrain from eating fruit and vegetables that offer a negligible risk of harm just because of fear, distrust, or an unwillingness or inability to pay the "organic farming" premium. The marketplace can provide some "organic", i.e. pesticide-free, produce, but at greater expense, with less availability, and with what may be a less appealing product.

Because exquisitely sensitive analytical techniques can detect a chemical in food does not in and of itself imply that the chemical represents a risk to health. With a few exceptions among non-cancer endpoints, most experts agree that levels of exposure to synthetic chemicals can be low enough to represent a negligible risk to health. In any circumstance, the decision to approve the presence of synthetic chemicals in our diet is a balancing act of benefit versus risk. A National Academy of Sciences report, Toxicants Occurring Naturally in Foods (1973), discussed this trade-off:

"..in balancing the benefits against the risks associated with the consumption of food additives and pesticide residues, the considerations used differ in some respects from those involved in thinking about the benefits and risks associated with the natural chemical constituents of our foods. The essential justification for the use of an additive in food processing - or of a pesticide that leaves a toxic residue in foods - is some direct or indirect benefit to the food consumer. Furthermore, it is a basic principle that the risks judged to be potentially associated with the use of any such substance should diminish with the importance of the benefit it is designed to achieve. An increased nutritional value, an increased food supply, availability or keeping quality, or a substantially decreased cost to the consumer are benefits that might be considered to justify a small degree of theoretical risk. An improvement in such superficial esthetic qualities of the food, however, as flavor, color, or consistency, that do not benefit the basic health or economic welfare of the consumer, are not acceptable bases for the use of a substance having a known or reasonably suspected risk..."

What we seek before this committee is a mandate to improve our knowledge of the hazards and risks attending the use of pesticide chemicals;

in so doing you will help build and maintain our trust in those delegated to make these difficult decisions. The American Psychological Association shares with this committee a concern about the effects of chemicals on health and the environment, and we stand ready to assist you as you deal with these problems.

Thank you for this opportunity to testify on this issue, and I would be pleased to answer any questions that you may have.

Attachment

TSCA Neurobehavioral Toxicity Test Guidelines

1. Neuropathology. Animals exposed to the test compound are euthanized and portions of their nervous systems are removed for the identification of lesions or structural abnormalities. This type of testing can identify exposure levels associated with frank neuropathology, but it is important to recognize that many neurotoxicants would not be detected in this procedure because they act by altering the function of the nervous system.

2. Peripheral neuropathy. This guideline utilizes electrophysiological procedures in animals exposed to the toxicant. Measures of nerve conduction velocity, response amplitude and chronaxy are used to evaluate the damage to the peripheral nervous system. These tests are very useful for identifying toxicants which produce peripheral neuropathies, but would not necessarily detect agents which directly affect the brain.

3. Delayed neurotoxicity. This is often called the "hen test". It is a very specific test for identifying cholinesterase inhibitors which produce delayed neurotoxicity. Its greatest application is for testing this class of pesticides. Hens and humans are particularly sensitive to this type of

neurotoxicity. In the "hen test", both behavioral and histopathological changes are evaluated after either acute or subacute exposure.

4. Neurotoxic esterase. This is a biochemical test for the formation of aged inhibited neurotoxic esterase, the form of the enzyme that produces the delayed neurotoxicity referred to above.

5. Functional observation battery. This is a very general screening test for evaluating neurobehavioral toxicants with unknown effects. It calls for the very systematic observation of the behavior of rats exposed to the test compound. The battery also includes measures of some reflexes and muscle control. Many chemicals acting upon the nervous system would be expected to alter one or more of the measures included in this battery. Thus, this test is particularly useful for initial evaluations. On the other hand, this test would not necessarily detect all neurotoxicants, especially those with a very subtle or selective effect. It would also be unlikely to detect an agent that affected higher processes such as learning or that produced personality changes.

6. Motor activity. Rats are usually used for this test as well. Mechanical counters are used to automatically record the level of general activity of exposed animals. This test is also a very general screening test for diverse types of neurobehavioral toxicants. Because the results

are quantitative, is is easier to use the data from this type of testing for establishing minimal levels of exposure associated with behavioral effects.

7. Schedule-controlled behavior. This test is designed to measure more subtle effects of possible neurotoxicants on learned behavior. Typically, rats are trained to press switches to obtain food and then they are exposed to the test agent. Methods from experimental psychology can be used to train animals to perform fairly complex behavioral sequences. This test is generally more sensitive and quantitative than typical screening tests and should be able to determine exposures with more subtle effects on behavior.

8. Developmental neurotoxicology. Research has shown that the developing fetus and very young organisms are often far more sensitive to neurotoxicants than adults. A number of animal models have been developed to examine the effects of prenatal and/or early postnatal exposure on offspring. Although a TSCA guideline has not been written for developmental effects, the EPA has a concern in this area and a test rule has been developed to obtain this type of data on at least one chemical. This test rule could be used to establish testing conditions for other compounds as well. This type of testing would be particularly important when exposures of pregnant women or very young children are anticipated.

- Neurobehavioral Effects Following Exposure to Toxic Substances

MOTOR EFFECTS
convulsions
weakness
tremor/twitching
lack of coordination/unsteadiness
paralysis
reflex abnormalities
activity changes

SENSORY EFFECTS
equilibrium changes
vision disorders
pain disorders
tactile disorders
auditory disorders

COGNITIVE EFFECTS
memory problems
confusion
speech impairment

MOOD/PERSONALITY EFFECTS
sleep disturbances
excitability
depression
irritability
restlessness
nervousness/tension
delirium
hallucinations

GENERAL EFFECTS
loss of appetite
depression of neuronal activity
narcosis/stupor
fatigue
nerve damage

SOURCE: Adapted from Anger, 1986.

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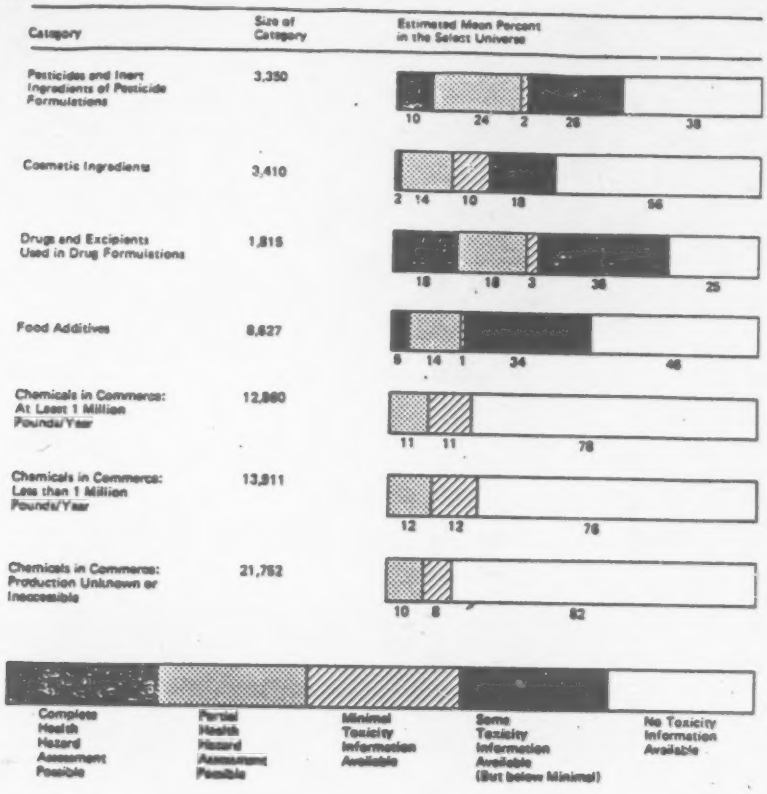
Chemical groupings in which 10 or more neurotoxic chemicals are found

Alcohols	Glycol derivatives
Alicyclic hydrocarbons	Halogenated aliphatic hydrocarbons containing Cl, Br, and I
Aliphatic and alicyclic amines	Halogenated cyclic hydrocarbons
Aliphatic carboxylic acids	Ketones
Aliphatic hydrocarbons	Metals
Aliphatic nitro compounds, nitrates, and nitrites	Nitrogen compounds
Aromatic hydrocarbons	Organic phosphates
Cyanides and nitriles	Organic phosphorus esters
Esters of aromatic monocarboxylic acids and monoalcohols	Organic sulfur compounds
Ethers	Phenols and phenolic compounds

Source: Clayton and Clayton 1981–82.



Ability to conduct health-hazard assessment of substances in seven categories of select universe.

SOURCE: 1984 National Academy of Sciences Report, Toxicity Testing: Strategies to Determine Needs and Priorities

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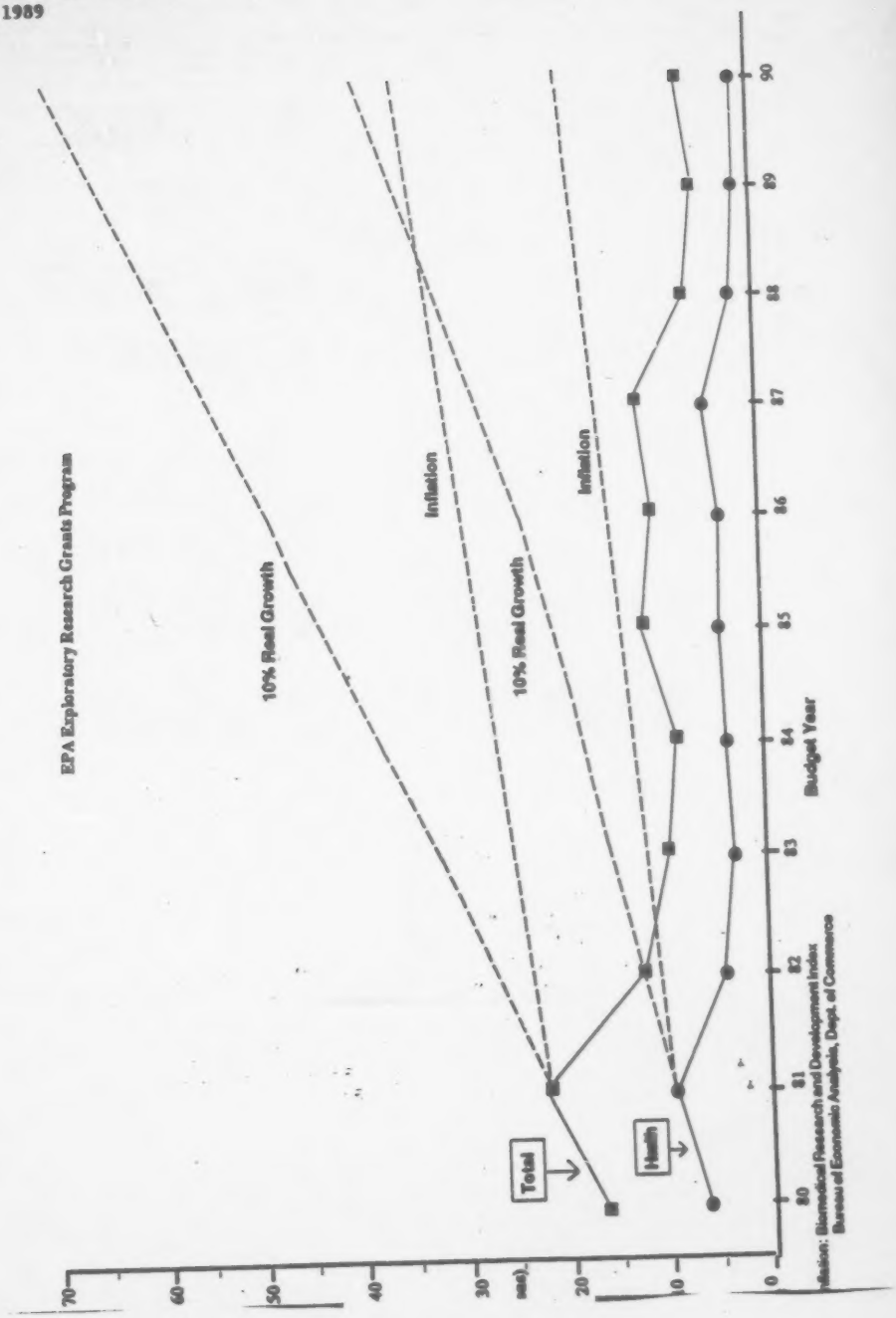

STATEMENT OF
JOHN A. MOORE
ACTING DEPUTY ADMINISTRATOR
U. S. ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE
SUBCOMMITTEE ON TOXIC SUBSTANCES, ENVIRONMENTAL OVERSIGHT,
RESEARCH AND DEVELOPMENT
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
UNITED STATES SENATE

MAY 15, 1989

Good morning, Mr. Chairman and members of the Committee. I am here today to report on the Environmental Protection Agency's progress to date in re-examining pesticides registered prior to November, 1984, known as old pesticides. At EPA, this activity is the highest priority for the pesticide program. We believe that we have made significant strides over the last few years through our reregistration and tolerance reassessment programs and our special review process. Through these programs, EPA has examined the available data on the most important old pesticides in use today, and we have removed from the market or severely restricted the use of a number of hazardous pesticides. Based on these actions we believe we can confidently say that pesticides in our food supply do not pose substantial risks, and that our food supply is among the safest in the world.

In my testimony today, I want to describe the Agency's reregistration, tolerance reassessment, and special review activities, and particularly what we have been doing over the last few months to implement the recently enacted Amendments to the

Federal Insecticide, Fungicide and Rodenticide Act, which we call FIFRA 88. Thanks to this legislation we expect to accelerate the pace of reregistration and special review of old chemicals. In my testimony, I will also discuss two of our more recent special review decisions -- on daminozide and captan -- and public reaction to these actions. I will also describe what EPA is doing about fungicides and organophosphate pesticides, two classes of pesticides identified in a recent report by the Natural Resources Defense Council (NRDC) as posing risks to our food supply.

While I think there are many accomplishments EPA may cite with pride, we cannot pretend that the challenge of reregistration will give us any chance to relax. Reregistration will undoubtedly force us to grapple with new questions on the cutting edge of scientific understanding. Reregistration, of course, will also probably lead to the identification of additional pesticides of public health or environmental concern. Dealing with these chemicals will strain, and perhaps overwhelm, our inefficient statutory processes for removing problem pesticides from the marketplace. Thus, in the conclusion to my testimony, I will describe how we think these future problems might be addressed.

Reregistration Activities

Reregistration is the systematic reexamination, using current scientific and regulatory standards, of all pesticide products containing any of more than 800 different active ingredients. Today, EPA requires up to 70 different kinds of tests, costing as

much as $10 million, on a major food use pesticide. During reregistration, EPA reviews existing studies on a pesticide and identifies and requires submission of additional tests that are needed to complete the reevaluation.

The reregistration program has made substantial progress since it was initiated in 1981. We have produced 194 Registration Standards at the rate of 25 per year on most of the important food use and other high exposure pesticide chemicals. These chemicals represent at least 85% of the total volume of pesticides manufactured in the U.S. annually. Each of these documents establishes a regulatory position and rationale for the current uses of the chemical, requires the generation of any additional data needed to support registration of products containing the chemical, and spells out any label changes needed to meet current standards. In many cases, additional use restrictions were identified for a chemical depending on the level of training or supervision of the applicator.

Although EPA has not formally "reregistered" any active ingredients, many pesticides have been removed from the marketplace as a result of EPA's activities. Aldrin, Chlordimeform, Chlordane, and Cyhexatin are some of the more familiar and important examples among the 24 chemicals out of the 194 that are no longer on the market. In addition, more than 50 other pesticides have been cancelled voluntarily or suspended by EPA. Thus, we believe that significant, tangible progress in protecting the environment has resulted from our reregistration activity.

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A few years ago the General Accounting Office studied EPA's reregistration program and called it a "formidable task." It certainly is. The FIFRA 88 amendments require EPA to accelerate the pace of reregistration and to complete the review of old pesticides in the next nine years. FIFRA 88 imposes a sequence of deadlines on pesticide registrants, who are responsible for supplying the complete test data bases necessary for EPA to make pesticide reregistration decisions. EPA must also meet very specific deadlines for publishing lists of pesticides thereby establishing the priority for reregistration review, for analyzing data submissions, and for deciding whether or not to reregister currently registered pesticides.

We have met every deadline that has come due under FIFRA 88 and we are on schedule for meeting the deadlines that are approaching. Reregistration will take place in five phases which define EPA and registrant responsibilities and deadlines. The first deadlines in the reregistration process (Phase 1) are for EPA to issue priority lists for the active ingredients contained in pesticides. List A -- chemicals for which registration standards have been issued -- was published in the Federal Register on February 22. It included 350 active ingredients in 194 standards, covering almost 24,000 products. On April 24, 1989, EPA issued List B, the first priority pesticide active ingredients for which Registration Standards had not been issued prior to the enactment of the amendments. The 150 chemicals on

List B include 230 active ingredients (structurally related chemicals are often grouped into one active ingredient case).

The remaining lists have been drafted and are undergoing internal review. They will be issued in accordance with the statutory deadlines (List C - 7/24/89, List D - 10/24/89). Guidance for registrants' responsibilities under Phase 3 of reregistration is required to be published by December 24, 1989, but we intend to beat that date by a substantial margin. This guidance includes:

-- Instructions for reformatting data for certain types of studies to facilitate EPA reviews;
-- Guidelines for summarizing existing studies and identifying instances where studies do not comply with established protocols but still contain valid findings; and,
-- Identification of studies indicating adverse effects.

Our senior scientists are working not only on this required guidance but also on additional guidance which we feel is essential to successful implementation. We will be providing the pesticide registrants and the public with clarification of existing data requirements and notice of proposed new requirements. This is necessary to insure that registrants' decisions to support pesticides for reregistration are based on as complete an understanding as possible of what data will be required and to

reduce the number of questions and discussions between EPA and registrants about requirements.

In addition, we are developing the detailed processes necessary to review the industry's responses on Lists B, C, and D. These processes include the development of advanced information systems to handle the anticipated flood of incoming data. We are also planning now for Phase 4 of reregistration when EPA independently identifies data requirements for Lists B, C, and D and we are continuing to place priority on the review of the List A active ingredients, since they are generally the most widely used pesticides and thus are likely to pose the greatest risks.

In sum, reregistration consists of a complex, difficult set of tasks, but we are proceeding expeditiously.

Tolerance Reassessment

As an integral part of the Agency's reregistration program, EPA also reassesses each pesticide tolerance (maximum legal residue allowed on food) established under the Federal Food, Drug, and Cosmetic Act. EPA looks especially carefully at tolerances existing for pesticides shown to be potential carcinogens. Traditionally, EPA and other Federal agencies consider risk that is on the order of one in a million or less to be negligible and for the most part has not set tolerances for risks that exeed that level. Since the Agency calculates a risk to an individual over a 70 year lifetime,

starting with exposure in childhood, these risk estimates include childhood as well as adult risks.

Regardless of the type of risks which may be associated with a pesticide, EPA sets tolerances at a level no higher than necessary to accommodate residues resulting from proper use, even if a higher level would not pose a health risk. If proper use would pose unreasonable dietary risks, the Agency generally would not set tolerances at all.

In setting new tolerances and reviewing existing tolerances, EPA is concerned about protecting sensitive subpopulations. EPA understands that some subpopulations -- especially infants and children -- receive higher than average exposure from certain foods. To guard against possible problems from such higher exposures, EPA routinely calculates and considers both a composite lifetime exposure for an average individual, as well as exposure values for over 20 subpopulations with potentially higher exposures -- including infants and children. Thus, EPA's analysis of pesticides in the diet takes into account that children and infants typically eat more food, in relation to their body weight, and more of certain types of food than the average adult. Using these exposure estimates, EPA evaluates average lifetime risk, as well as the risk for subpopulations with higher exposures. Generally, EPA bases its tolerance decisions on the composite average lifetime risk which includes the proportionately greater exposure that may occur in childhood. The calculations for other subpopulations allow us to ensure that no particular group receives exposure which

is likely to cause unreasonable risks. This sophisticated approach, which allows us to account for subpopulations, is the result of improvements in the process which have been implemented over the past several years. We will continue to apply this approach systematically to the reevaluation of old chemicals during the implementation of the FIFRA 88 amendments.

Special Review, Cancellation, and Suspension

The nine-year deadline imposed by FIFRA 88 represents an improvement over our old reregistration schedule. However, it nevertheless means that we cannot reevaluate at once the safety of all old pesticides. As EPA obtains and reviews information on old pesticides, we will identify some which may pose previously unrecognized risks to people or the environment. We will then need to use our Special Review, cancellation, and suspension procedures to restrict or prohibit the use of these chemicals. Limiting the use of these chemicals or getting them out of the marketplace is, however, usually a slow, resource-intensive process.

Once a pesticide is tagged as a potential problem, EPA generally conducts an intensive and systematic review of the risks and benefits to determine whether, under FIFRA, the use of the pesticide causes "unreasonable adverse effects on the environment." This process, known as "Special Review," provides opportunities for public comment; it currently takes from one and a half to four

years to formulate an Agency position on whether to cancel the pesticide use, or to allow continued use subject to restrictions.

Once EPA has determined how it intends to regulate a pesticide, FIFRA requires that the Agency send its proposed notices of intent to cancel to a group of independent scientific experts, the Scientific Advisory Panel. The Panel members, who serve 4 year terms, are selected by EPA from nominees from the National Institutes of Health and the National Science Foundation. Panel members are subject to Federal laws governing conflicts of interest. The Panel provides comment on the scientific basis for proposed regulatory actions. Although EPA has not always agreed with the Panel's comments and on occasion has declined to follow the Panel's recommendations, I believe that, on the whole, the Panel has contributed to an across-the-board improvement in the quality of the scientific analyses on which EPA has based its regulatory decisions.

After evaluating comments on its proposed decisions -- from the Panel, USDA, and the general public -- EPA concludes the Special Review process by issuing a final determination, usually in the form of a Notice of Intent to Cancel Registration. This notice may be challenged in a trial-like administrative proceeding before an EPA Administrative Law Judge, whose decision may be appealed to the EPA Administrator. Pending the Administrator's decision, no regulatory restrictions are imposed on the pesticide or its use. The decision at the end of a cancellation hearing,

which can come a number of years after the notice of EPA's intent to cancel, may then be challenged in a federal court of appeals. Thus, registrants can get up to three "bites at the apple" -- three different chances to object to EPA's proposed action -- during the Special Review process, the cancellation proceeding, and judicial review.

In certain limited circumstances, EPA can act more quickly. To remove a pesticide from the marketplace immediately, EPA must have in hand data which show that an "imminent hazard" exists and that there is an "emergency". EPA may ban the sale and use of a pesticide, effective immediately, if such an emergency exists but historically EPA has made imminent hazard and emergency findings only three times for major pesticides -- for ethylene dibromide (EDB), 2,4,5-T, and dinoseb. For chronic hazards, EPA expects such cases to be equally rare in the future.

Let me turn now to some decisions on specific pesticides.

Alar

Recently, EPA announced its decision to accelerate the Special Review of pesticide products containing the active ingredient, daminozide, sold under the brand name Alar. Using carefully evaluated toxicology and exposure data, EPA estimated that the theoretical risk of developing cancer from a lifetime of exposure to Alar exceeded one in a million. The Agency found the data compelling enough to expedite the process which will result in a final cancellation decision after the proposed action has been made

available for public comment. In fact, I plan to issue a draft cancellation notice for Alar sometime in May.

Many people, however, have criticized EPA for not taking stronger action, such as issuing an emergency suspension of Alar products. Calls for more expedited action often cite the risk estimates announced by NRDC -- risk projections which we believe to be overstated and scientifically suspect. The NRDC's risk estimates appear in a report entitled "Intolerable Risk: Pesticides in Our Children's Food," which concludes that there is a massive and imminent public health problem from pesticide residues in food, and in particular from Alar residues in apples and apple products. While I believe Alar residues should be removed from the nation's food supply -- to make a safe diet safer -- to eliminate a dietary risk that is unacceptable from a long-term perspective, Alar residues do not pose a short-term risk of a magnitude which indicates an imminent, overwhelming harm.

The NRDC has calculated the cancer risk attributed to Alar and its breakdown product, UDMH, to be over 100-fold greater than EPA's traditionally conservative estimate. NRDC used cancer potency estimates from data on UDMH which were rejected by our independent Scientific Advisory Panel in 1985. The Panel questioned the appropriateness of using these data for generating risk assessments for regulatory purposes. We have since required Uniroyal Chemical Co., Inc., which makes Alar, to conduct new cancer studies, and EPA has based its current risk estimates on preliminary results from these new studies.

NRDC also made, we believe, inappropriate use of food consumption data in generating its estimates of exposure. In addition, while the food consumption data used by NRDC were more recent, they were based on a small survey (2100 people) which had relatively poor participation (only a 65% completion rate). EPA used a much larger survey conducted by USDA in 1977-78 (over 30,000 people were surveyed) which had an extremely high completion rate (over 95%). (That survey is currently being updated to reflect 1987/88 data.)

Furthermore, let me emphasize that risk estimates are theoretical calculations, which are based on animal testing, are fairly rough upper limits, and are not precise predictions of human disease. EPA uses a procedure to estimate risk which incorporates a 95% confidence limit on the potency calculations and a variety of other technical assumptions. We characterize our estimates as upper bounds in the sense that the true risks are not expected to be higher than this, and may well be lower-- even zero. Unfortunately, qualifications like these are not well understood outside the scientific community. In the public debate, statistical projections are perceived with absolute certainty as resulting in fatal cancer cases.

It is important also to note that risks are likely to be considerably lower today than EPA's recent estimate. We have data indicating a significant reduction in the use of Alar has already occurred. EPA estimates that Alar is only used by approximately 5-15 percent of the Nation's apple growers, down from 24 percent

when the Agency expressed serious concern about the continued use of Alar in 1985. Many supermarkets and food processors have pledged to sell or use only untreated apples. While residues have been found in apples and apple products of firms that have said they have stopped using treated apples, the levels that have been found are generally quite low. The most recent monitoring data by Consumers Union and other organizations generally reveal fewer samples with detectable levels than found in a 1986 market basket survey used by EPA for our current risk estimates. We expect current usage will further decline as a result of our proposed cancellation action.

Captan and Other Fungicides

EPA is also concerned about the potential risks of the fungicides and has taken several recent actions to reduce these risks. On February 24, 1989, EPA announced its decision to cancel a number of the food use registrations for the fungicide captan while retaining others. For some of the uses of captan still allowed, the Agency will also reduce the tolerance levels. Individually and cumulatively the 24 uses of captan that are being retained pose a theoretical lifetime cancer risk of one in a million. The 42 cancelled captan uses reflect an Agency sentiment that residues of a probable chemical carcinogen should not be permitted without a clear indication of benefits from use. The Agency's action to retain major uses of captan also reflects our

finding that the benefits of some uses of captan outweigh the risks from dietary exposure.

As in the case for Alar, the NRDC has calculated the theoretical cancer risk attributed to captan to be nearly 100-fold greater than EPA's traditionally conservative estimate. Several factors contribute to the discrepancy between the NRDC and EPA estimates. The NRDC combined cancer potency estimates from animal studies in different species in a way that EPA believes to be scientifically inappropriate. EPA estimated its cancer potency estimate using the approach, generally endorsed by the scientific community, of selecting data on the most sensitive species exhibiting tumors in a valid study. The NRDC's higher estimates are also based in part on food consumption data EPA considers to be of uncertain reliability.

Folpet is a broad-spectrum fungicide which was used on a variety of crops, including fruits, berries, and vegetables, and is another fungicide the NRDC cites as contributing to the cancer risk to children. The Agency was also concerned about its potential to cause oncogenic and reproductive effects. Due to the extensive data requirements requested by the Agency, all food uses of folpet were voluntarily cancelled by the registrant in June 1987, more than 18 months before the NRDC report was issued.

Finally, EPA is also considering regulatory action on a group of fungicides that belong to the same chemical family ethylene bis-dithiocarbamates, the EBDC's. These chemicals are currently in

Special Review and the Agency expects to propose a final decision on these chemicals in the next few weeks.

Organophosphate Pesticides

The Agency has not seen evidence that the legal limit of organophosphate insecticides residues in food are causing adverse health effects in children, as indicated in the NRDC report. There are, nevertheless, many issues important for the identification and characterization of neurotoxic substances. We are currently revising our testing requirements for pesticides to include more extensive testing for effects on the nervous system. A subpanel of our FIFRA Scientific Advisory Panel met to review the Agency's plan to adopt the guidelines developed under the Toxic Substances Control Act for the assessment of neurotoxic effects resulting from exposure to pesticides. The subpanel generally endorsed the adoption of these guidelines and recommended routine testing of pesticides for observation of neurologic signs, motor activity, and neuropathology. We also plan to test certain classes of chemicals for developmental neurotoxic effects, that is animals exposed in the womb will be tested after birth for behavioral changes and neuropathology. Most of these tests can be readily incorporated into the standard toxicity testing currently required for all pesticides. The Agency is currently working on revising these neurotoxicity guidelines based on our experience to date. The first set of guidelines, encompassing the first tier of tests which

may be required, are expected to be ready for review by the Panel and the public during the summer.

Meeting the Challenges of the Future

Even though EPA believes our general risk assessment methodology is sound and our tolerance setting system is protective of public health, our system is not perfect. Over the years as we have recognized aspects that need improvement, we have taken steps to strengthen the process. Our efforts have focused on gathering better, more complete data about pesticides, refining our ability to estimate dietary exposure, and reducing other areas of scientific uncertainty associated with risk assessment. Examples of such activities include: developing the Tolerance Assessment System (TAS), a computer model which enhances our ability to evaluate dietary exposure of different subgroups including infants and children in the U.S. population; commissioning a National Academy of Sciences study on the regulation of carcinogenic pesticides ("The Delaney Paradox") which recommended a "negligible risk" approach to setting tolerances such as was applied to captan and is under consideration for the EBDC's; and commissioning the National Academy of Sciences to study the issue of whether children and infants are more sensitive to the toxic effects of pesticide residues in their diet than are adults.

This latter NAS study, begun in 1988, will examine the methods employed to assess risk posed by pesticides in the diets of infants and children and will make recommendations on whether changes are

needed in the Agency's risk assessment process. In discussing this study, the Academy said: "This study derives from the general consensus in the scientific community that new methods may be available to improve risk assessment methods and better protect the public health. It is important to note, however, that this study does not arise from the documented increase in any disease or adverse health condition in infants, children, or adults resulting from exposure to legal levels of pesticides in the diet." We expect to receive the report of this study in 1990.

In addition to these initiatives, I support proposals to require registrants to develop better analytical methods for measuring pesticide residues and to generate more data when necessary on actual residue levels in food. I also agree with those who seek to increase consumer understanding of the risks and benefits of pesticide use and to increase education for farmers on alternative, cost-effective pest control methods that could aid in reducing pesticide applications.

And as many members of Congress know, I have repeatedly stated the need for changes in the law to allow us to get a pesticide off the market more quickly and easily once a problem has been identified. We are considering suggestions for how we might accomplish this goal. One of these is to replace the existing cancellation process with a notice and comment procedure, similar to the existing Special Review process. This would eliminate the second "bite at the apple."

Conclusion

I welcome constructive debate on pesticide issues; such a debate can only lead to a better system for all of us. These issues should not be divisive; we all want to protect public health. But if misinformation and fear dominate the debate, there is a very real chance that we will make poor decisions. If that happens, it is the public -- including our children -- who will bear the consequences of our failure.

Testimony of
Dr. John F. McCarthy
Vice President for
Scientific and Regulatory Affairs
Before
The Toxic Substances, Environmental Oversight,
Research and Development Subcommittee
of the
Committee on Environment and Public Works
U. S. Senate
May 15, 1989

Mr. Chairman, I am greatful for the opportunity to testify today, on behalf of the National Agricultural Chemicals Asscciation (NACA)*. Needless to say, we have a vital interest in the subjects of this hearing..... The EPA regulatory process, neurotoxicity issues and how carcinogenic risks are dealt with, especially the issue of fungicides. Let me deal with those subjects in that order.

THE EPA REGULATORY PROCESS

We are concerned, and saddened, over the messages the American public has been receiving on this subject the last couple of years. The public has been under a constant barrage of communications from self-appointed watchdogs who are saying there is considerable and imminent danger from eating produce because it has been seriously "contaminated" by uncaring farmers "pouring" on pesticides without any consideration to the benefits to consumers. And, the whole process is regulated with a deadly mixture of indifference and incompetence by the bureaucrats of

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* The National Agricultural Chemicals Association (NACA) is a nonprofit, trade organization of manufacturers and formulators of pest control products employed in agricultural production. NACA's membership is composed of the companies which produce and sell virtually all of the technical crop protection materials (active ingredients) and a large percentage of the formulated products registered for use in the United States.

the Environmental Protection Agency and the Food and Drug and Administration. Is this a fair impression? It's not only unfair, it's untrue. The tactics used by those spreading such messages have bordered on "toxic terrorism". As an editorial in the April 7, 1989 issue of Science Magazine (a weekly publication of the highly prestigious American Association for the Advancement of Science), entitled "Scare of the Week" pointed out that it is time to recognize that public interest groups have conflicts of interest as just as do business groups. They also noted that these groups, while they contribute to our society, should be held accountable for their acts -- just like the rest of us.

So, is the process working? Yes. Is is perfect? No. Can we make improvements? Yes. So what does the agricultural chemicals industry advocate -- implementation of the 1988 amendments to the Federal Incesticide, Fungicide, and Rodenticide Act (FIFRA '88) without a hitch and increased monitoring of the food supply. I would like to elaborate on each of these briefly.

FIFRA '88

The main controversy swirling around the pesticide issue has been the adequacy of data on the "older pesticides". In 1972, Congress passed a new FIFRA which required that the "older pesticides" be brought up to current standards. The process was termed reregistration. I would like to stress that pesticides registered prior to 1972 were tested. Tolerances were

established for food use pesticides by the Food and Drug Administration under the Federal Food Drug and Cosmetic Act. FDA required chronic toxicity studies (2-year rat, 2-year dog, and 3-generation reproduction studies), residue studies, and analytical methods suitable for enforcing tolerances. The studies were done and the results evaluated according to the scientific standards of the day. The notion that pesticides registered before 1972 weren't tested is simply false.

Considerable difficulty was encountered in implementing this program during the 1970's. There is enough blame to go around. However, the program is now on track. FIFRA '88 not only provided much needed clearer direction, but gave EPA the resources to do the job. For example, the agricultural chemical industry will pay $170 million over the next 9 years in fees for this program. This is over and above the investment our industry is making in retesting and upgrading of data. So far, the process is working. EPA is meeting the deadlines stipulated by the legislation. The FIFRA '88 Implementation Task Force has gone out of their way to communicate with our industry on the intricacies of implementation. We can't say enough good things about that. We hope this open communication will continue. Our industry wants FIFRA '88 to work. We can't afford misunderstandings or diversions. Needless to say, there will differences of opinion arising from the interpretation new data. We are hopeful these can be resolved swiftly through the application of good sound science.

There is a concern we have at this point concerning FIFRA '88 implementation. It is that EPA is having difficulty attracting the necessary scientists. A particular problem they appear to be having is recruiting toxicologists. We also note, from a recent press report, EPA and OMB are at odds over the extent of the use of contractors. We hope these differences of opinion can be resolved swiftly so the Agency can get on with implementing the law in a manner which they believe is in the best interests of everyone.

There are two final points before concluding my remarks on this topic. The first is that we are not starting the reregistration process from ground zero. And the second is we need to let the process work free from interferences of new unnecessary legislative mandates which would place additional burdens on the agency.

Registration standards, documents which identify new data requirements, have been issued over the last 9 years for 194 active ingredients. These are the so-called "List A" chemicals in the terminology of FIFRA '88. These 194 chemicals represent approximately 90 percent by weight of pesticides used. The list contains the major food use chemicals. EPA has also placed special priority on food use chemicals through their data call-in program. This is a program in which the Agency has identified critical health and safety studies which are missing. Over the

past ten years, data call-ins have been issued for 350 food use chemicals. What all this means is that the upgrading of data is well underway.

While we acknowledge we don't live in a perfect world, new legislative initiatives which would place unnecessary burdens on the EPA should be avoided. The reregistration process must be allowed to work.

Monitoring of the Food Supply

We have testified before Congressional Committees on previous occasions that increased appropriations be given to the Food and Drug Administration to step-up their surveillance program. We believe FDA is doing a good job despite enormous resource constraints. FDA believes that both raw agricultural commodities and processed foods marketed in this country are safe. We believe that also, along with leading scientists and prestigous scientific bodies.* But the confidence of the American public in this safety is paramount. We believe that increased surveillance would strengthen and bolster that confidence.

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* We draw attention to a report released April 5, 1989 entitled, "Assessing the Optimal System for Ensuring Food Safety: A Scientific Consensus". The report is from 14 scientific societies representing 100,000 food scientists, microbiologists, toxicologists and veterinarians. The report concluded the food supply is safe, and the threat from pesticides is more calculated than real. Attention is also drawn to a recent report of the National Research Council entitled "Diet and Health: Implications for Reducing Chronic Disease Risk". In this most exhaustive study on diet and health to date, the Committee found no evidence to suggest food additives or pesticides make a major contribution to the risk of cancer in humans. They stressed increased consumption of fruits and vegetables as a means of preventing cancer.

We would also like to add that the California Department of Food and Agriculture (CDFA) has a surveillance program as large as FDA's. Their results are consistance with FDA's -- less than one per cent of commodities tested exceed tolerances and extremely low levels (the majority with no detectable residues) in the remainder.

NEUROTOXICITY

The use of this term has been abused. Not everything which has an effect on the nervous system should be judged as "neurotoxic". Substances which inhibit the enzyme acetyl cholinesterase (the enzyme which clears the nerve junction of acetylcholine thereby stopping impulse transmission) without neurological damage or impairment should not be considered "neurotoxins".

There are a group of insecticides which are classified as acetylcholine esterase inhibitors. Chemically, they are organophosphate and carbmate pesticides. EPA requires tests for delayed neurotoxicity with these substances (such tests are required for other compounds which there is reason to believe they have a direct effect on the nervous system). FDA formerly required these tests also. This test determines whether or not a substance causes demyelination (destruction) of the myelin sheath (protective shield) around the nerve. Substances which cause such delayed neurotoxicity are not registered by EPA. To the best of our knowledge, there are no pesticides on the market which have such effects.

The issue has been raised as to whether or not other kinds of tests should be done to detect other neurotoxicological and behavioral effects of pesticides. NACA supports neurotoxicological and behavoral effects testing as a legitimate component of the requirements for registration and reregistration. We supported amendments to FIFRA in 1986 and 1987 which stated:

> "The Administrator shall develop methods for testing to accurately detect neurotoxicological and behavoral effects of pesticides, and their ingredients, and shall, as such methods are developed, require to the extent appropriate and necessary, that data from such testing be submitted by persons seeking to obtain or maintain pesticide registrations."

This language was developed jointly by NACA and the Center of Science in the Public Interest and agreed to by the Coalition for Pesticide Reform as part of the negotiated legislative package introduced originally in Congress during 1986.

Even though the 1986 and 1987 amendments didn't pass, we still support this principle. We publicly reaffirmed our position on this question to a special FIFRA Scientific Advisory Panel Subpanel on neurotoxicity on October 15-16, 1987. Basically NACA's view on this matter is as follows: Current testing is not devoid of observations which signal neurotoxicological or behavioral effects. However, a more systematic set of observations could be added to current testing procedures, specifically to the 90-day rat study. These procedures are termed "functional observational battery" and "motor activity". In addition, supplementary neuropathology

could be included. These procedures could be done "across the board" with all pesticides. Further testing for neurotoxicity should only be required on a case-by-case basis. That is, when "positive" results are obtained from across the board tests. Our position on this is essentially the same as recommended by the FIFRA SAP Subpanel to EPA. It is our understanding EPA is preparing to release testing guidelines for public comment and further SAP review this summer.

CARCINOGENIC RISKS OF FUNGICIDES

The issue of fungicides was highlighted in the 1987 report of the National Academy of Sciences (NAS) Regulating Pesticides in Food: The Delaney Paradox. The use of the information in that report has been abused. The report is a policy document, not a risk assessment document. The Chairman and members of the NAS Committee stressed on numerous occasions that the numbers in the report should not be looked upon as real risk numbers. The Report states, "The reader should focus on general patterns of risk distribution and how key parameters change when policy alternatives are assessed, not on specific point estimates of risk." What surfaced from this analysis was that fungicides should be looked at more closely. The main message of the study was that there should be a consistent negligible risk standard applied to oncogenic pesticides on both raw and processed foods. They rejected the notion of a zero risk standard which is now stipulated by the Delaney Clause. NACA supported the NAS recommendations. So what has happened since 1987?

EPA has published (October 19, 1988) their policy for implementation of the negligible risk recommendations contained in the 1987 NAS report. NACA supports this policy.

The policy has recently been applied to the fungicide Captan. It is being applied to the EBDC fungicides. EPA's regulatory proposal on this group of fungicides (zineb, maneb, metiram and mancozeb) are due to be published this month. I would also like to note that the fungicides Captafol and Folpet, which were identified in the NAS report, are no longer used on food crops. What these actions are telling us is that the process is working.

There is one final point. We agree with the Agency that a legislative solution to the Delaney Paradox would be desirable and that such legislation ideally would give the latitude to establish tolerances and food additive regulations for pesticides under a risk/benefit standard compatible with FIFRA, with a definitive statement that clearances for both raw and processed foods are to be established under a risk/benefit approach.

Mr. Chairman, we thank you for the opportunity to testify before this Subcommittee and would be happy to answer any questions you or the members have.

Natural Resources
Defense Council

1350 New York Ave., N.W.
Washington, DC 20005
202 783-7800

TESTIMONY

OF

JANET S. HATHAWAY

ON BEHALF OF THE

NATURAL RESOURCES DEFENSE COUNCIL (NRDC)

BEFORE THE

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

SUBCOMMITTEE ON TOXIC SUBSTANCES, ENVIRONMENTAL

OVERSIGHT, RESEARCH AND DEVELOPMENT

UNITED STATES SENATE

CONCERNING NRDC'S FEBRUARY 1989 REPORT, "INTOLERABLE RISK:

PESTICIDES IN OUR CHILDREN'S FOOD"

MAY 15, 1989

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415 777-0220

Natural Resources
Defense Council
212 Merchant St.
Suite 203
Honolulu, HI 96813
808 533-1075

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Thank you for the opportunity to testify before this Committee about NRDC's recent report, "Intolerable Risk: Pesticides in Our Children's Food." I am Janet Hathaway, senior project attorney with NRDC. The Natural Resources Defense Council (NRDC) is a non-profit organization of attorneys and scientists dedicated to protecting public health and the environment. NRDC has worked to reform the laws and policies governing pesticide use for more than a decade.

I. NRDC's Methodology

Two years ago NRDC began this study to ascertain whether actual levels of pesticide residue in our preschoolers' diet pose a significant risk to our children's health. We collected government data on the diets of preschool children, pesticide residue levels, and risks posed by 23 of the approximately 300 pesticides legal for use on food in the United States. Of these 23 pesticides, the Environmental Protection Agency (EPA) identified 8 as potential cancer-causing chemicals and 15 as capable of causing neurotoxic effects, or damage to the nervous system.

NRDC estimated the health risk to preschoolers during their first six years of life (0-5 years) by determining consumption rates for 27 fruits and vegetables most frequently eaten by children. Preschoolers' exposure to these 23 pesticides was determined by combining children's consumption rates for the 27 food types with actual pesticide residue levels found in these

foods. Pesticide exposure estimates were then assessed to determine the preschoolers' risk of developing cancer or experiencing a disruption in central nervous system function.

To develop an adequate database of preschooler exposure to pesticides, NRDC used consumption data from a nationwide food consumption survey of children and adult women conducted in 1985 by the U.S. Department of Agriculture (USDA). The data on the residues of the 23 pesticides were derived from analyses of over 12,000 samples of the 27 fruits and vegetables obtained by regulatory programs of the Food and Drug Administration (FDA) and the EPA.

II. Principal Findings of "Intolerable Risk."

NRDC concludes that preschoolers are being exposed to hazardous levels of pesticides in fruits and vegetables. Between 5,500 and 6,200 (a risk range of 2.5×10^{-4} to 2.8×10^{-4}) of the current population of American preschoolers may eventually get cancer solely as a result of their preschool exposure to eight pesticides or metabolites through eating fruits and vegetables during their preschool years.[1] These estimates are based on scientifically conservative risk assessment procedures. They

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[1] These estimates are based on the eating habits of preschool children who participated in the 1985 USDA survey and who responded to the survey three or more times over the course of a year. These data were used to approximate average daily exposure over the year. However, cancer risk estimates were also made based on daily intake for all preschoolers in the survey and result in an estimated 5,700 to 6,400 additional cancer cases (2.6×10^{-4} to 2.9×10^{-4}) in the preschool population.

indicate that more than 50% of a person's lifetime cancer risk from exposure to carcinogenic pesticides used on fruit is typically incurred in the first six years of life.

The potent carcinogen, unsymmetrical dimethylhydrazine (UDMH), a breakdown product of the pesticide daminozide, presents nearly ninety percent of the cancer risk identified by NRDC. The average preschooler's UDMH exposure during the first six years of life alone is estimated to result in a cancer risk of approximately one case for every 4,200 preschoolers exposed. This is 240 times greater than the cancer risk considered acceptable by EPA following a full lifetime of exposure.[2] For children who are heavy consumers of the foods that may contain UDMH residues, NRDC predicts one additional case of cancer for approximately every 1,100 children, 910 times EPA's "acceptable" risk level.

The carcinogenic risk estimates for UDMH are based on results of a 1986 market basket survey that EPA required the manufacturers of daminozide to conduct. Although daminozide use may have decreased since 1986, there is no reliable information on whether--or to what degree--use has decreased. (See discussion in Section V, Part C, on page 14).

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[2] Using daily intake for all preschoolers in the survey (see footnote 1), UDMH still accounts for the majority of the cancer risk. The risk calculated by NRDC for the first six years of life is 250 times the level EPA considers acceptable following a full lifetime of exposure.

Preschoolers also receive unacceptable exposure to the carcinogenic fungicides captan, chlorothalonil, folpet, and ethylene thiourea (ETU), the metabolite of the fungicide mancozeb. NRDC estimates that average exposure to these pesticides from consumption of 27 fruits and vegetables from birth through age five may present a lifetime risk of one cancer case for every 33,000 to 160,000 children exposed. That means that out of the current preschool population, between 140 to 670 children may develop cancer sometime during their lifetime as a result of exposure to these fungicides. These risk estimates are approximately two to seven times what EPA considers acceptable following a full lifetime of exposure. These estimates are unchanged by EPA's recent decision to cancel certain minor food uses of captan since none of the food uses contributing to preschoolers' risk in our calculation were cancelled by EPA.

NRDC found that at least 17% of the preschool population, or three million children, receive exposure above levels the federal government considers safe to neurotoxic organophosphate insecticides just from eating raw fruits and vegetables. High level exposures to these insecticides can cause nausea, convulsions, coma and even death. The lower exposures received by preschoolers through their diets may induce behavioral impairments and alter neurological function.

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III. Explanation of Children's Enhanced Risk

NRDC's analysis of exposure, based on studies of food consumption by children and women, determined that relative to their weight preschoolers receive much greater exposure than adults to the majority of the pesticides analyzed in this report. The average preschooler receives more than five times greater exposure to the fungicide mancozeb, nine times greater exposure to the neurotoxic organophosphate azinphos-methyl and 12 times greater exposure to UDMH, the carcinogenic metabolite of daminozide, than adults. The typical preschooler receives four times greater exposure, on average, than adults to the eight carcinogenic pesticides evaluated. The youngest children receive the greatest pesticide exposure. Relative to adult women, toddlers receive more than eight times the exposure to mancozeb, 15 times greater exposure to azinphos-methyl and 18 times greater exposure to UDMH, than women.

Preschoolers have greater exposure to pesticide residues than adults because they eat more food, relative to their weight, and consume much larger quantities of fruit, which has a high likelihood of being contaminated with pesticides. Fruit comprises 20% of the adult diet and 34% of the preschooler's diet. Preschoolers eat six times as much total fruit, seven times more grape products and seven times more apples and apple sauce, relative to their weight, than adults. Apple juice is a particular favorite of children. The typical preschool child consumes almost 18 times as much apple juice and the typical

toddler more than 31 times as much apple juice, relative to their weight, as the average adult woman.

Fruit is highly likely to contain pesticide residues. The 1987 FDA's food monitoring program found that 50% of all fruit samples had detectable levels of pesticides. This contamination rate is higher than that of any other commodity and may significantly underestimate the full extent of contamination. Routine FDA monitoring methods cannot detect approximately 60% of the pesticides likely to leave residues on food, including many carcinogenic fungicides used widely on fruit.

IV. NRDC's Findings May Underestimate Preschooler Risk.

The NRDC study may significantly underestimate the full extent of preschooler exposure and the subsequent health risk from pesticides in food for several reasons. First, this study assesses cancer risk that results from exposure only from birth through age five to pesticides in food. The total lifetime cancer risk will be greater since estimates do not include risk incurred from age six to 70+ years. Further, this study assesses the health risk from only 23 pesticides out of the 300 that can be legally used on food. Of the 66 pesticides EPA believes to be potentially carcinogenic and allows to be used on food, only eight were evaluated by NRDC. Routinely used FDA monitoring methods--from which much of the residue data used in the NRDC analysis were obtained--can detect only approximately 40% of the pesticides likely to leave residues on foods. Of all food use

pesticides classified by the federal government as posing a moderate to high health hazard, approximately 40% cannot be detected by FDA monitoring techniques.

NRDC has only assessed exposure from 27 fruits and vegetables out of the many commodities that are consumed daily by preschoolers and that may contain pesticide residues. Milk products are perhaps the most conspicuous of the foods absent from the exposure estimates. The average preschooler has a milk intake that is almost five times higher than that of the typical woman. EPA estimates that 60% or more of the preschooler's exposure to the carcinogenic fungicide captan, for example, may come from residues in milk. EPA's recent cancellation of some minor food uses of captan does not appear to reduce this estimated exposure from milk. Pesticides get into animal products, including meat and eggs, as well as milk, via pesticide-contaminated feed. Drinking water may also be a significant source of pesticide exposure, especially in rural areas. EPA has reported that the normal agricultural use of pesticides has resulted in detectable pesticide concentrations in the groundwater of 26 states.

This report focuses primarily on the risk of developing cancer or disruption of normal nervous system function from dietary exposure to pesticides. However, many of the pesticides in the study may cause additional adverse health effects, such as damage to the kidney or liver, effects on the immune system, or changes in reproductive capacity. Further, the full impact on

preschooler health from exposure to pesticides is unknown since the majority of the 600 active pesticide ingredients (representing 50,000 pesticide products actually in use) have not been tested in accordance with modern testing requirements. The National Academy of Sciences (NAS) concluded in 1984, based on an analysis of a representative sample of pesticides, that data needed to conduct a complete health hazard assessment were available for only 10% of the pesticide products on the market. Of the 23 pesticides evaluated for NRDC's study, 19 (83%) were registered by USDA in the 1950s and 1960s before any comprehensive testing requirements were in place. EPA simply adopted their registrations, despite the paucity of scientific data on health effects.

NRDC's study probably underestimates the risks to children for a number of other important reasons. Children are likely to be more susceptible to the effects of nervous-system toxins and cancer-causing chemicals than we have assumed in making our estimates. However, data regarding the degree of enhanced sensitivity in preschoolers were not available for the specific pesticides evaluated in this report; therefore, susceptibility could not be factored into our health risk assessment.

The government does not require adequate testing for neurotoxic effects of pesticides. Long-term neurological testing for chronic effects of organophosphates and other neurotoxic pesticides is not required; the current tests assess only if the

pesticide is capable of causing a specific delayed paralytic reaction following acute and subacute exposure.

Finally, "inert" ingredients, which are used to dilute, propel or stabilize the active ingredients, are not regulated, even though many are known to cause cancer or other health hazards. Moreover, EPA has historically not required submission of health or safety information on "inerts". These compounds, labeled "inert" because they are not effective against the pest for which the product was designed, have been exempted from federal requirements for setting permissible residue levels for pesticides in food. Among the inert ingredients known to be hazardous are benzene, carbon tetrachloride, chloroform, formaldehyde, lead and methylene chloride. The exposure to such dangerous "inert" ingredients was not quantified in calculating risk from consumption of pesticides in food.

V. Responses to NRDC's Critics.

Criticisms of the report have been leveled by EPA officials and representatives for organizations such as Uniroyal, the manufacturer of the pesticide daminozide, and the International Apple Institute. NRDC continues to stand behind our methodology and our conclusions. We wish to reply to some of the charges which have been made about our report.

A. The International Apple Institute Claims that a Person Must Eat 28,000 Pounds of Apples per Day to Approximate the UDMH Exposure Levels Received by Laboratory Animals.

The apple industry is using sophistry to deflect attention from the real risk posed by UDMH. All of the government's risk assessments are performed by extrapolating from high dose animal experiments to the lower doses expected in the human population. NRDC's risk assessment is no different. We know that children are exposed to UDMH in apples, peanuts and other commodities in low concentrations. The pertinent question is whether the levels of exposure are likely to result in a real health hazard. We determined that even at actual exposure levels, the hazard is significant.

NRDC studied the actual pesticide residue levels and children's actual consumption levels. We did not assume that children eat the same amount of UDMH as was ingested by laboratory animals. To the contrary, from 1985-1986 USDA data we determined that the average preschool child consumes approximately <u>one ounce of apple and two ounces of apple juice per day</u>.

We also knew that UDMH levels were relatively small even in foods which had been treated with daminozide. Daminozide's manufacturer, Uniroyal, submitted to EPA data on the residue levels found in 1986 in a variety of commodities -- such as apples, cherries, peanuts and grapes -- on which daminozide is used. According to Uniroyal, these commodities contained average UDMH levels ranging from approximately 1 to 100 parts per <u>billion</u>. Even at the parts per billion level in foods which are heavily consumed by preschool children, UDMH poses a significant

carcinogenic risk. We estimate a risk of one cancer for every 4200 preschool children based on children's average consumption of foods containing UDMH residues. Children's consumption of apple products contributed 74% percent of the total risk from UDMH exposure in preschooler's diets.

Therefore, the International Apple Institute is simply wrong to imply that consumption of 28,000 pounds per day over a 70-year lifetime is needed to create a hazard for the human population. As our data demonstrate, preschoolers' consumption of only a few ounces per day of commodities containing very low levels of UDMH poses a significant health hazard.

B. EPA Challenges NRDC's Use of the UDMH Cancer Potency Factor Derived from Pre-1985 UDMH Cancer Studies.

EPA has stated that a discrepancy in the dietary UDMH cancer risks calculated by NRDC and EPA results from the fact that NRDC and EPA used different cancer potency factors, or measures of carcinogenic potential, in calculating the risk from UDMH. While this is true, NRDC believes that we used the correct cancer potency factor to estimate the risk posed by UDMH.

NRDC used the UDMH potency factor which EPA calculated in 1985 from long-term animal tests performed to evaluate the cancer risk from UDMH by researchers at the Eppley Institute for Research in Cancer and Allied Diseases, University of Nebraska Medical Center. EPA evaluated this and other studies to conclude in 1985 that UDMH was a "probable human carcinogen" and to

recommend the cancellation of daminozide's uses.[3] However, in September 1985, following a one-day hearing before EPA's Scientific Advisory Panel at which the chemical's manufacturer, Uniroyal, objected to the studies, EPA reversed its recommendation. EPA decided that the pre-1985 studies were insufficient to quantify the cancer risk and granted Uniroyal the right to continue to sell daminozide for use on food for the years it would take for Uniroyal to perform its own cancer studies on daminozide and UDMH.

Why did EPA refuse to regulate daminozide based on the numerous studies which associated its breakdown product, UDMH, with rare blood vessel tumors in laboratory animals? EPA concluded that none of the studies were suitable for calculating the number of people likely to develop cancer from exposure to daminozide and UDMH in food, because most of these studies were old and were not performed in accordance with EPA's most recently developed testing protocols. NRDC acknowledges that the pre-1985 studies had flaws, but none of the flaws were so serious as to warrant ignoring the data from these independent researchers. No one suggests that the pre-1985 data was fabricated or basically invalid. Instead, the old studies, despite their flaws, consistently demonstrated that the chemical UDMH is a potent

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[3] Environmental Protection Agency, "Daminozide Special Review Position Document 2/3/4," Draft, September 12, 1985, p. II-30.

carcinogen, a fact which both the EPA and its Scientific Advisory Panel acknowledged in 1985.[4]

NRDC used EPA's 1985 UDMH cancer potency factor because we believe it constitutes the best available estimate of the cancer risk posed by UDMH. The pre-1985 studies are the only completed cancer studies on UDMH. Although the pre-1985 cancer studies may be imperfect predictors of the cancer risk posed by UDMH, we believe that it is imperative for regulatory agencies to regulate based on the best available data instead of futilely waiting for perfect knowledge. NRDC believes it indefensible to allow chemicals which are repeatedly proven to cause tumors in animal experiments to remain in the food supply awaiting a consensus concerning the magnitude of the human risk.

On February 1, 1989, based on data from the halfway point in a new Uniroyal UDMH study, EPA announced concern about the occurrence of statistically significant increases in unusual blood vessel tumors in mice. From this study EPA estimated an alternative cancer potency factor which is lower than that derived from the pre-1985 studies.[5] We believe that the pre-1985 laboratory tests form a reasonable basis for estimating the

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[4] EPA, Scientific Advisory Panel, In the Matter of: Intent to Cancel Registration of Pesticide Products Containing Captan [including discussion of regulatory action to be taken on the daminozide (Alar) Position Document 2/3/4], September 27, 1985, transcript of proceedings, Part II, p. 12-13.

[5] NRDC requested, but was not given, EPA's revised UDMH cancer potency factor before we released our report.

cancer risk from UDMH in the absence of completed, more reliable long-term animal studies.

It is important for the Committee to note that even EPA's February 1, 1989 estimation of the dietary cancer risk from UDMH, while lower than the NRDC estimate, is 45 times EPA's self-proclaimed standard for "negligible" cancer risk, one cancer in an exposed population of one million. Therefore, whether one uses EPA's UDMH cancer potency factor derived from Uniroyal's 1988 interim report, or whether one uses EPA's 1985 UDMH potency factor, the risk to the population -- and particularly to children -- from the daminozide breakdown product is unacceptably high, even by EPA's own standards. NRDC believes that the magnitude of the risk warrants immediate EPA action to curtail the use of daminozide in food.

C. EPA and the Apple Industry Claim that Only Five Percent of Apples were Treated with Alar in 1988.

EPA has repeatedly stated that approximately 5% of apples are treated with daminozide, and therefore that the risk is lower than that estimated by NRDC. However, the five percent figure was derived by EPA's staff from informal conversations with growers, who may have a strong self-interest in portraying their products as daminozide-free. In contrast to EPA's figure, one Uniroyal manager privately stated that 10-11% of the nation's apple acreage was treated with daminozide in 1988.[6]

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[6] Personal communication with Paul Bohne, Manager of Research and Development for the Northeast, Uniroyal, February 21, 1989. (continued...)

Further, an independent laboratory found in 1988 that 30% of apples tested from one large supermarket chain--which claimed to be selling only daminozide-free apples--in fact contained detectible daminozide.[7] More recently, a survey indicated that 23% of Vermont's apple acreage was treated with daminozide.[8] These data were not considered when EPA developed its use estimate and raise serious questions about the accuracy of the Agency's figure. In the absence of comprehensive government testing to verify grower claims about daminozide use, the manufacturer's 1986 market basket survey remains the only accurate indicator of actual residues in food.

There is other evidence that the five percent use figure cited by EPA greatly underestimates apple growers' use of the chemical in 1988.

*** The Food and Drug Administration found daminozide in 38% of the apples it tested in 1988.

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[8](...continued)
Mr. Bohne's estimate assumes that all Alar sold domestically was applied at the maximum legal rate. Because in fact some growers used the chemical at lesser rates, more total acreage was treated.

[7] NutriClean, Inc., Certificate of Laboratory Results, [Daminozide in Safeway Apples], January 29, 1988; see also Schneider, Keith, "Safeway Accused of Breaking Promise on Apples," New York Times, p. A23, February 3, 1988.

[8] Costante, J.F., "1988 Vermont Apple Crop Statistics for Commercial Use," The Apple Press, University of Vermont Extension Service.

*** In February 1989, Consumers Union, publishers of Consumer Reports, found 55% of the apples sampled from New York City stores contained daminozide.

*** In April 1989, the Los Angeles Times commissioned an independent laboratory to test apples and found daminozide in 40 percent of the apples tested.

These studies suggest that the correct use figure is substantially greater than EPA's estimate and does not differ markedly from the use level reported by Uniroyal in 1986, on which NRDC based its risk estimates.

D. Environmental Protection Agency Disputes NRDC's Use of USDA 1985-1986 Consumption Data.

EPA has questioned NRDC's risk estimates in part because NRDC derived them from a United States Department of Agriculture 1985-1986 dietary study which surveyed the eating habits of nearly 500 children. EPA's Tolerance Assessment System, the data base which EPA plans to use to set future legal limits for pesticide residues in food, is based on a larger 1977 USDA survey. NRDC believes that our use of the 1985-6 diet survey was appropriate and provides the best estimate of current food consumption patterns.

Despite the relatively small sample size, USDA designed the 1985-6 survey to reflect regional and cultural diversity in food consumption. Participants were selected to represent a variety of demographic factors believed to influence dietary habits.

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The 1985-6 USDA diet survey was superior to the 1977 survey because it evaluated respondents' diets over a period of at least several months. This resulted in a dietary survey which followed an individual's food consumption through different seasons and idiosyncratic variations. Because what we eat on any one day is unlikely to serve as an accurate predictor of what we eat year-round, NRDC considers the 1985-6 diet survey a more useful indicator of dietary habits.

The 1985 USDA data is also particularly useful because it enables one to contrast children's consumption (and hence their pesticide exposure) with that of adult women. The fact that children consume more fruit per body weight than their parents is significant, and should be quantified by those seeking to regulate pesticide exposure.

Finally, NRDC feels that the more recent USDA survey is probably more representative of food consumption patterns today. For decades, Americans have been told to increase their intake of fresh fruits and vegetables. The 1985-6 USDA survey indicates substantially greater consumption of fresh fruits and vegetables than did the 1977 survey relied on by EPA, probably reflecting the fact that many Americans have taken doctors' advice. The trend toward higher fruit and vegetable consumption is important in evaluating dietary pesticide exposure, because many pesticide residues occur at greater frequency and in higher concentrations in these commodities. NRDC's use of the 1985-6 USDA food survey is more likely to accurately assess present dietary pesticide

exposures than would be possible through use of the earlier USDA study.

VI. EPA'S PROGRAM TO PROTECT THE AMERICAN FOOD SUPPLY FROM PESTICIDE CONTAMINATION HAS BEEN A FAILURE.

The ongoing public controversy about EPA's failure to protect the general population, and especially children, from dangerous pesticides in foods is not an isolated incident. On the contrary, it is the latest in a decade-long series of failures by the federal government to fulfill their responsibilities under the Federal Food, Drug and Cosmetic Act (FFDCA). The Agency's record in this regard has been marked by regulatory foot-dragging, inordinate influence by the chemical industry, and twisted analyses of clear mandates under the Act. The result is that dangerous levels of cancer-causing chemicals remain in our food.

Last year, the EPA Administrator announced that the health risks presented from pesticides in food were being elevated to the Agency's number one priority. In doing so, a high-level EPA official said, "Pesticides dwarf the other environmental risks the Agency deals with. Toxic waste dumps may affect a few thousand people who live around them. But virtually everyone is exposed to pesticides." Unfortunately, as recent events involving daminozide and captan make clear, this rhetoric has not been reflected in an actual change in Agency practice.

Examples of EPA's historical failures that have contributed to this "pesticide of the year" syndrome are legion. Perhaps the best example of the lack of effective EPA pesticide regulation before daminozide was the pesticide ethylene dibromide (EDB). In 1974 the National Cancer Institute first determined that "there is strong evidence that EDB is likely to cause cancer in humans." Ten years later, the chemical remained on the market. It had languished for many years in the EPA "special review" (then called RPAR) program, the same cancellation process now being relied upon to regulate daminozide. In late 1983, EDB residues were found in the nation's grain supply, in citrus crops and other foods, as well as drinking water. Several states including Florida, New York and California, took regulatory action. Following a great deal of public clamor, and Congressional hearings severely criticizing the Agency, the EPA Administrator William Ruckelshaus then banned the chemical.

The danger from EDB was primarily due to a high dietary cancer risk. For the population as a whole, EPA calculated the additional risk of getting cancer from eating foods contaminated with EDB to be roughly three in 10,000 with the "realistic worst case" of 1.5 in 1,000. In a population of 200 million people, these risks translate to as many as 70,000 to 300,000 additional cancers over a lifetime from exposure to EDB in food. The chemical also is a powerful reproductive toxin.

A year prior to the EDB experience, the nation was startled to learn that much of the milk supply in the state of Hawaii had

been contaminated for several months with the pesticide heptachlor, a pesticide banned in the continental United States after being linked to leukemia and neurological disorders. Heptachlor had been sprayed on pineapple leaves which were then fed to dairy cows, resulting in high concentrations in milk and other dairy products. After this discovery, the government failed to act for several months. Finally the Food and Drug Administration required the destruction of 90 percent of the milk on the island of Oahu. Heptachlor continued to turn up in breast milk long afterwards. And, more recently, heptachlor again found its way into the news when its residues were found in the milk supply in several southwestern states.

Other examples of agricultural chemicals which EPA has ineffectively regulated include DBCP, a close relative of ethylene dibromide and a powerful carcinogen finally banned by EPA in 1979; toxaphene, finally banned by the Agency in the mid-1980s; carbon tetrachloride and other grain fumigants, which presented both acute risks to workers and high cancer risks to consumers; and the acutely toxic pesticide aldicarb (or Temik), which caused numerous miscarriages and other adverse health effects and the illegal use of which resulted in confiscation of more than a million watermelons in California. Examples such as daminozide, EDB, heptachlor and DBCP are not the exception to a thoughtfully-considered and well-executed public policy: they are instead the rule. Without fundamental legislative change making clear the Agency's principal responsibility to protect

public health from these toxic chemicals, we expect to repeat the daminozide experience once again.

The EPA record reflects bureaucratic intransigence even when the Agency confronts a serious cancer risk. Under Sections 408 and 409 of the Federal Food, Drug and Cosmetic Act, it is the duty of the Agency to protect the health of all citizens, including the young. Permitting cancer risks several hundred times higher than the level of risk EPA now classifies as "negligible" does not fulfill that statutory mandate. Moreover, contrary to views recently expressed by various EPA spokespersons, the burden of demonstrating that the residue of a pesticide in food is fully protective of public health lies squarely on the pesticide industry and not the government.

In addition, EPA continues to incorrectly interpret the Federal Food, Drug and Cosmetic Act's strict anti-cancer provision, the "Delaney" clause. The Agency flatly refuses to apply this provision "retrospectively" to chemicals already on the market. Recently, Assistant Administrator John Moore stated publicly that while he would not register daminozide for use on food today because of data demonstrating carcinogenicity, his hands were tied in preventing its continued use.[9] This position has no basis in logic or in law. The Agency's belief that the Delaney prohibition against carcinogens in processed foods, now contained in Section 409 of the Act, applies to new chemicals

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[9] "A is for Apple," CBS's "60 Minutes," February 26, 1989.

coming on the market but was not intended by Congress to apply to so-called "old pesticides" that have now been tested and determined to be carcinogens finds no support in the legislative history of the FFDCA or in the laws' basic intent to protect the public from cancer-causing chemicals.

EPA's position is directly contrary to the view of the Food and Drug Administration, the agency principally charged with carrying out the requirements of this Act. In recently articulating this position in a Federal Register notice[10] the EPA acknowledged that their principal rationale for their interpretation of the Delaney clause was that otherwise Section 409 would require certain old pesticides to be removed from the market. This was the result that Congress intended and that protecting public health requires. In that same Federal Register notice, EPA contended that even for new pesticides, Section 409 permitted a "de minimus" risk of one in a million from pesticides used in food. This position has been decisively rejected by the courts most recently in Public Citizen v. Young.[11]

Finally, as we have noted in "Intolerable Risk", EPA continues to fail to meet its existing legal obligations to act to remedy the serious health risks presented by so-called "inert" ingredients in the food chain. Food use pesticides contain both an active ingredient and an inert ingredient, the latter usually

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[10] "Regulation of Pesticides in Food: Addressing the Delaney Paradox Policy Statement," Federal Register, October 19, 1988.

[11] Public Citizen v. Young, 831 F.2d 1108, (D.C. Cir. 1987).

used as a stabilizer, diluent or carrier for the active. While many of these inert ingredients are not acutely toxic to the target organism, many are far from benign. EPA has now classified 57 inert ingredients as of toxicological concern, including such substances as benzene, vinyl chloride, zylene and asbestos.[12] Nevertheless, all inert ingredients have been granted blanket exemption from the tolerance-setting requirements of the Food, Drug and Cosmetic Act. These substances are simply allowed to exist in the food supply without any regulation -- even when the substances are indisputably toxic or carcinogenic. The Agency is empowered to grant exemptions from the tolerance requirements of the Federal Food, Drug and Cosmetic Act only when the chemicals present "no hazard to human health." Yet EPA has failed to act to revoke these improper exemptions for dangerous inert ingredients.

In short, for more than a decade, EPA's record of protecting the food chain from hazardous pesticides has been characterized by a failure to carry out its principal mandate: protecting the American consumer from the health risks presented by these most toxic of chemicals. The failure of the government to act forcefully and without inordinate delay contributes to a general distrust of Agency regulation.

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[12] EPA has identified 57 inert pesticide ingredients as posing "toxicological concern." Fed. Reg. 13305 (April 22, 1987).

VII. RECOMMENDATIONS FOR REFORM OF LAWS GOVERNING PESTICIDES IN FOOD.

Residues of pesticides with known toxic effects are widely present in the food supply. In particular, these residues pose a serious health threat to preschoolers. This public health problem is largely the result of inadequate regulation on the part of the federal government. Immediate action is necessary to close the loopholes in EPA's and FDA's regulation of pesticide residues in food. Further, Congress must act to assist growers in reducing their use of pesticides. The implementation of the following recommendations is necessary to assure the safety of the food supply.

A. Congress Must Require EPA to Protect the Public From Pesticide Residues In Food.

The Federal Food, Drug and Cosmetic Act governs the types of pesticides, and the concentrations of residues, which can legally occur in our foods. Tolerances, or legal limits on pesticide residues, are set by EPA under the FFDCA. EPA will be collecting important new data on the health and environmental effects of pesticides as a result of the 1988 amendments to FIFRA[13], but it is not clear when or whether EPA will use these data to reestablish tolerances at new levels which will truly protect the public health.

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[13] Federal Insecticide, Fungicide and Rodenticide Act Amendments of 1988, Pub. L. 100-532, October 25, 1988.

Ten fundamental EPA reforms are needed to ensure the safety of our food supply from pesticide residues.

1. EPA Should Rapidly Establish New, Protective Tolerances for All 23 Pesticides Which Are the Subject of NRDC's Study.

For all of 23 chemicals which are the subject of NRDC's study, EPA should rapidly set legal limits which ensure that any residues of these chemicals persisting in our food supply do not present a hazard to preschoolers. It should take no longer than one year for EPA to set new, protective tolerances for the 23 chemicals in this report.

2. EPA Should Swiftly Reassess and Reestablish Tolerances for All Pesticides for which EPA has Received New Health and Safety Data. For Pesticides which are only now being Studied for Health Effects, EPA Should Never Take Longer Than One Year After Receiving New Studies to Establish Appropriate New Tolerances.

Pesticides in food are legal up to the tolerance level. Yet residues are not necessarily safe in those amounts, or, as NRDC's "Intolerable Risk" report illustrates, even at levels well below tolerance. This situation has occurred in part because most pesticide tolerances were set in the absence of reliable and complete data on the effects of long-term exposure. In fact, many existing tolerances were established by USDA prior to EPA's existence and were set with great deference to the economic interests of growers. Because the health effects of chronic low-level exposure were generally unknown, tolerance levels often only reflected residue levels resulting from growers' historical uses. Tolerances were routinely set high, so that crops

subjected to the most frequent and most concentrated permissible pesticide treatments could legally be sold. EPA inherited these old tolerances from USDA when it was created in 1970. Unfortunately, many of these old, high tolerances still remain on the books. Tolerances are not systematically reassessed and revised as EPA receives new data indicating the potential of pesticides to cause cancer and other chronic effects.

This situation is exacerbated by the fact that even today, only a handful of the approximately 300 pesticides legally used on food have adequate, full data on the threat they pose to human health from chronic dietary exposure. Amendments to the federal pesticide law, FIFRA, enacted in October 1988 will require pesticide manufacturers to test their products fully in the next few years and EPA to reassess the safety of chemicals completely within nine years. Tolerance revision should occur immediately when EPA learns of new or higher risks than were assumed when the legal limit was initially set.

3. EPA Should Ensure That the Most Exposed and Most Vulnerable Members of Society--Infants and Children--are Adequately Protected From Pesticide Residues.

EPA's pesticide risk assessments and the resultant regulatory decisions assume an "average" diet. However, virtually every individual's diet deviates considerably from that of an average American's. Most people eat high quantities of certain foods and avoid other foods altogether. The consequence is that EPA's pesticide tolerances are designed to protect the

theoretically average consumer--not the actual person who eats an apple, or two, a day. Consumers who eat higher quantities of any food than EPA considers to be average are not necessarily protected by EPA tolerances from developing cancers or other diseases caused by pesticides remaining on food.

As NRDC's study illustrates, EPA's reliance on the average diet is particularly inappropriate for preschoolers. For example, the average preschooler consumes almost six times as much fruit, five times as much milk, and almost three and a half times as many grain products per unit of body-weight as the average adult woman.[14] The difference for specific foods is often much greater. Clearly, children are not "average" consumers. Pesticide limits should be set to protect children and other "non-average" eaters. EPA should revise existing tolerances and establish new tolerances, based on the unique dietary intake of preschoolers and any other especially vulnerable or highly exposed subgroup of the population.

4. EPA Must Revise Exposure Estimates. Potential Exposure at the Legal Maximum--the Tolerance Level--Should be Assumed When EPA Conducts Risk Assessments.

EPA has not routinely lowered tolerances upon a finding that the legally permissible concentrations of pesticide residues would cause high risk of cancer or other adverse effects. EPA

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[14] USDA, Human Nutrition Information Service, CSFII-Nationwide Food Consumption Survey: Continuing Survey of Food Intakes by Individuals, Women 19-50 Years and Their Children 1-5 Years, 6 Waves, 1985.

often dismisses these findings by stating that residues are normally below tolerance levels, but EPA does not concomitantly lower the tolerances to what it has declared to be the "normal" level. Consequently, people may unwittingly consume foods that, although legal, contain pesticide levels which EPA's data demonstrate to be unsafe.

Legal food should be safe food. Without prohibitively expensive chemical analyses of all food, consumers cannot identify which foods bear high residues and which have lower, safer concentrations of pesticides. Therefore, EPA should ensure that consumption of food with residues at the legal maximum is safe. EPA should perform risk assessments based on the assumption that pesticide residues will be present at the maximum legal concentration. If growers or the food industry believe that such a risk assessment overstates the risk, they should demonstrate that actual residues are less and petition for a lower legal limit.

5. EPA Should Use the Most Current Information on Dietary Consumption to Set All New Tolerances and Should Revise All Existing Tolerances With These More Accurate Data.

EPA defends many old tolerances and even sets some new tolerances by reference to consumption estimates which tend to underestimate human dietary exposure. EPA's outdated consumption estimates ("Food Factors") presume that people eat no more than 7.5 ounces annually of many common foods including almonds, avocados, blueberries, cantaloupe, eggplant, honeydew melon,

mushrooms, nectarines, and tangerines. These estimates greatly understate preschooler dietary consumption. For instance, preschooler intake of cranberries is 14 times greater than the comparable Food Factor, grape consumption is six times greater, apples and oranges approximately five times greater, apricots almost four times greater, and strawberries almost three times greater.

EPA now has more accurate data on food consumption derived from a 1977 USDA dietary survey, which EPA incorporated into a database called the Tolerance Assessment System (TAS). EPA began using TAS in the fall of 1986 for extremely limited purposes. The TAS data have not been used to revise one single older tolerance initially established with the outdated Food Factors.

Even the TAS data are now almost a decade old, and American dietary habits have changed in the interim. For example, preschoolers' consumption of fruits and vegetables has increased 30%, and fruits alone by as much as 45%, between the 1977 and 1985 USDA dietary surveys.

TAS can be used to examine the dietary intake of subgroups of the population, such as preschoolers. However, EPA primarily utilizes the TAS data on average adult consumption. EPA should immediately update TAS with the most current dietary intake data. EPA should examine the dietary exposure of the most exposed group in the population, which usually is children. All EPA tolerances, existing or new, should be established on the basis

of TAS, at levels which ensure that even at preschooler consumption levels, pesticide residues will not endanger health.

6. EPA Must Ensure That Cumulative Exposures to a Variety of Pesticides in Foods, in Drinking Water, and in Our Homes are Considered When Tolerance Levels are Set. It is the Cumulative Risk Which the Actual Person Experiences, and That Risk Must be Minimized.

EPA's pesticide tolerances do not now ensure that exposures to all legally present pesticides in our food are safe. EPA's tolerance-setting is premised on the obviously erroneous assumption that we are exposed only to a single pesticide over our lifetimes. In fact, nearly 300 active ingredients in pesticides are registered for use on food and several may be present on a single strawberry or carrot. In 1984, NRDC analyzed pesticide residues in fresh produce purchased in grocery stores in San Francisco. NRDC found that two or more pesticide residues were present in 42% of the samples bearing identifiable residues.[15]

But when EPA sets a tolerance level, EPA only calculates average risk from exposure to a single pesticide. The reality is that there may be several pesticides, which increase our risks of cancer or neurotoxic effects, present in a single meal. EPA currently fails to ensure that the cumulative risk of eating foods containing many carcinogenic or neurotoxic pesticides is safe.

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[15] Mott, Lawrie and Martha Broad, Pesticides in Food: What the Public Needs to Know, NRDC, March 15, 1984.

EPA also should consider that consumers are exposed to many of the same pesticides used in foods in their drinking water and in their homes. An insecticide used to combat roaches in one's kitchen may be inhaled in small concentrations for months to come. When EPA permits the insecticide to be used on food crops, EPA should ensure that the total exposures from uses in the home, in the garden, and in agriculture are at a safe level. EPA should consider the cumulative risk from all routes of exposure to a pesticide when setting tolerances. At a minimum, the Agency should factor drinking water exposure to pesticides into the tolerance-setting process -- especially because EPA now has substantial data on pesticide contamination of ground and surface water supplies.

Toxicologists know that in some instances exposure to a combination of toxic chemicals can result in a much higher incidence of cancers or other adverse health effects than would be expected from merely adding the predicted effects of each chemical. For example, smokers who were exposed to asbestos suffered far higher rates of lung cancer than were predicted by simply summing the risks of cigarette smoking and asbestos exposure. Synergistic interactions have been documented between organophosphate insecticides, such as disulfoton and phosalone, methamidiphos and malathion, and EPN and malathion. Synergism and other non-additive effects of pesticides have not been adequately studied. EPA should require testing of pesticides which are commonly used in combination for synergistic effects.

In the absence of data demonstrating synergism, EPA should at least consistently assume that the effects of multiple pesticides are additive. In fact, the Agency has adopted guidelines for assessing the additive health risk from exposures to chemical mixtures.[16] This approach is a good starting point for determining the health effects from simultaneous exposure to several pesticides. Although difficult to consider in establishing tolerances, synergism should not be dismissed by EPA as it could seriously exacerbate health consequences. This is particularly true for exposures to organophosphates. EPA should explore methods to factor consideration of synergism into pesticide regulatory actions.

7. EPA Must Prohibit the Use of Dangerous "Inert" Ingredients in Pesticides.

EPA's current tolerance-setting procedure also ignores the risks posed by the so-called "inert" ingredients in the pesticide. Inerts are chemicals used to carry, dilute, or stabilize the "active" ingredients which effectively weaken, repel or kill the pest. Many of the "inerts" are dangerous chemicals in their own right.[17] Carcinogenic "inerts" include asbestos, benzene, carbon tetrachloride, chloroform and formaldehyde. Neurological damage may occur from "inerts" such

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[16] EPA, "Guidelines for the Health Risk Assessment of Chemical Mixtures," 51 Fed. Reg. 34014 (September 24, 1986).

[17] In 1987, EPA published a list of 57 inerts of "toxicological concern." 52 Fed. Reg. 13305 (April 22, 1987).

as hexachlorophene and lead. EPA's tolerances are based on a clearly erroneous presumption that the "inert" ingredient will not contribute to injury or illness. EPA should prohibit the use of dangerous "inert" ingredients.

8. EPA Must Require Pesticide Registrants to Develop Analytical Detection Methods Which Can be Routinely Used by the Government in Enforcing the Pesticide Laws. Such Methods Must be Swift, Accurate, and Feasible for the FDA Laboratories.

Pesticides should not be used on food if FDA cannot readily detect the residues in food. Without the ability to detect residues at reasonable cost, FDA cannot enforce EPA's tolerances and therefore cannot protect the public from pesticide residues in food.

EPA should require that manufacturers of pesticides used on food develop practical methods for detecting pesticide residues. An analytical method should be considered practical only if the method: (1) reliably and routinely quantifies the level of residue in food with sensitivity sufficient to enforce the tolerance; (2) provides results in less than eight hours; (3) can be used in FDA labs with existing FDA laboratory equipment; and (4) costs no more than what is typically incurred by the FDA in using a multi-residue method. A practical method could be an individual pesticide scan. However, broader multi-residue methods should be sought, where feasible.

9. Congress Must Clarify EPA's Authority to Revoke or Modify Tolerances Swiftly When Pesticides in Our Diet are Found to Present Significant Risk. EPA Needs the Authority to Revoke a Tolerance Automatically When Data Needed for Evaluating a Tolerance are Not Submitted According to EPA's Deadlines.

The Federal Food Drug and Cosmetic Act includes glacially slow, cumbersome procedures which EPA must follow when seeking to modify or revoke an old tolerance. Congress must revise these procedures. Even when pesticide makers fail to submit required toxicology data, EPA is unable to immediately halt the use of the chemical on food. Dr. John A. Moore, EPA Assistant Administrator, stated at a congressional hearing last year that it was likely to take years to remove a pesticide from the market, even when the manufacturers flagrantly violate a data-submission requirement of the law.[18] EPA's supposedly rapid Special Review process to investigate the hazards of dangerous pesticides takes many years. For example, the EBDCs have been undergoing special investigation since 1977. When EPA finally determines that a pesticide tolerance poses a significant hazard, they must be empowered to act rapidly to revise the tolerance. EPA must also have authority to act immediately when a pesticide poses a serious health risk.

10. EPA Must Require Systematic Testing of all Pesticides for Their Potential to Cause Neurological Damage.

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[18] Testimony of John A. Moore, Assistant Administrator for Pesticides and Toxic Substances, EPA, before the House Energy and Commerce Committee, Regulation of Pesticides Hearing, June 8, 1987, p. 172.

EPA has not routinely required pesticide manufacturers to investigate the possible effects of pesticides on the nervous system. Even when EPA requires some study of the neurotoxic effects of a pesticide, it asks only for data which indicate at what levels the pesticide causes paralysis and death. Many chemicals are now known to have far more subtle but deleterious effects on the nervous system. For example, studies suggest that exposure to organophosphates and carbamate pesticides before and immediately after birth can cause delays in reflex and sexual development, delays in eye opening, alter nerve transmission function and neuroreceptor development, impair neuromuscular function, alter brain electrical activity, and affect brain structure. EPA needs to know what effects chronic, low-level exposure to pesticide residues may have on motor coordination, memory, behavior, learning and intelligence. Neurotoxicity testing should be required for all pesticides used on food, and the testing should evaluate both acute and long-term adverse effects.

B. Legislation is Needed to Ensure That FDA's Program to Monitor for Pesticides in Food is Improved.

Food safety cannot be achieved by EPA reforms alone. The Food and Drug Administration has responsibility to monitor for most pesticides in food. For commodities other than meat, milk, poultry and eggs, for which the USDA has responsibility, FDA enforces the laws concerning food safety.

At least seven major FDA reforms are needed:

1. FDA Must Improve Its Methods to Detect Pesticides in Food.

FDA monitoring for pesticides is inadequate to ensure that residues are legal, let alone safe. Of the 496 pesticides FDA has identified as likely to leave residues in food, FDA's routine analytical methods can only detect 203--only 41%.[19] Of the 105 pesticides which FDA considers to pose a moderate to high health hazard, only 58 (55%) are detectible using the FDA multi-residue methods.[20] Among the commonly used pesticides which cannot be detected by FDA's multi-residue methods are benomyl, daminozide, the EBDC fungicides and paraquat.[21] Twenty-six of the 53 pesticides identified by EPA as potentially oncogenic for the 1987 NAS report on pesticides in food cannot be detected by FDA's multi-residue method.

2. Pesticide Use Information is Crucial to the Improvement of FDA's Pesticide Monitoring Program. Use information should be required to maintain a tolerance.

FDA, with the assistance of other federal agencies and growers, should develop accurate, detailed pesticide use information for both domestic and imported produce. FDA cannot effectively use single-residue analytical methods to supplement the multi-residue pesticide screens because it has very limited information on which pesticides are used on each crop. FDA

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[19] GAO, Pesticides: Need to Enhance FDA's Ability to Protect the Public From Illegal Residues, October 1986, p. 33.

[20] Ibid, p. 36.

[21] Ibid, p. 39.

chemists would be wasting their time using monitoring methods capable of detecting only a single pesticide unless the government had fairly solid evidence that the pesticide, in fact, was applied to the crop during growing, storage or transportation.

Even with domestically grown crops, FDA lacks reliable pesticide application records. Often, FDA choice of the monitoring method must be based on educated guesses about what pesticides were likely to have been used. Some pesticide use information can be gleaned from USDA, state agencies, the food industry, and grower cooperatives, but the data vary significantly in comprehensiveness and reliability. According to the Resources for the Future, only nine states prepare pesticide usage reports on most crops, 17 states report only on major crops, and 15 other states prepare usage reports of more limited value.[22]

With regard to imported foods, FDA has even less knowledge about the pesticides which may remain on them. FDA relies heavily on a private pesticide-use database which provides aggregate information for only 12 countries that export produce

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[22] Gianessi, L. and C. Puffer, Resources for the Future, "The Availability of State-Level Pesticide Use Data: A Status Report," November 1986, Table I.

to the United States.[23] Dozens of other countries ship significant amounts of fresh fruits and vegetables to the United States. Many pesticides which are banned in this country--such as DDT and EDB--are used in agriculture in countries from which we import substantial quantities of fruits and vegetables. Pesticides like omethoate are not registered for use in the U.S. but are used in other countries on produce which may be exported to this country. Additionally, pesticides which have limited legal uses in the United States may be used on entirely different crops abroad. Therefore, FDA must have accurate information about pesticide use, both domestically and abroad, in order to adequately monitor our food for pesticide residues.

3. FDA Must Cut Delays in Analyzing Samples.

FDA must also decrease the time lag between sample collection and release of the results of the pesticide analysis. The General Accounting Office (GAO) found that between October 1, 1983 and March 31, 1985, FDA laboratories took an average of 28 calendar days to analyze samples for pesticide residues.[24] Eighty-three percent of 179 illegal samples were not analyzed within the two-day period FDA said was usually needed for

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[23] FDA's pesticide use information is primarily based on the Battelle World Agrochemical Data Bank. The Battelle data are limited to the following 13 countries: the United States, Japan, India, Brazil, France, Italy, Indonesia, Spain, South Korea, Mexico, South Africa, Turkey and Egypt.

[24] GAO, Food and Drug Administration: Laboratory Analysis of Product Samples Needs To Be More Timely, September 1986, p. 3.

intercepting the food prior to sale to consumers.[25] Congress should require FDA to increase the speed of its analyses of food samples; and to ensure that FDA removes food with illegal residues from the market before it is sold or consumed.

4. FDA Should Track the Disposition of Foods Bearing Illegal Pesticide Residues, and Should Ensure that Appropriate Sanctions are Imposed on Violators of the Pesticide Laws.

FDA should initiate a system to track the disposition of all food samples found to contain illegal pesticide residues. In 1986, GAO reported, "In 107 of the 179 cases in which FDA found that food contained illegal pesticide residues, it did not take any action to prevent food from reaching the market because the food had already been sold."[26] According to GAO, in only one of the 179 identified incidents of illegal pesticide contamination did FDA seize all of the illegal food. Penalties and other sanctions for violators are imposed only rarely.

FDA should routinely collect and publicly report the Agency's disposition of food containing violative concentrations of pesticides. Such information is crucial for assessing FDA's effectiveness at preventing public exposure to unsafe levels of pesticides in food. Such reports would also help Congress judge the adequacy of FDA's sanctions against those responsible for violating pesticide tolerances.

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[25] GAO, Pesticides: Need to Enhance FDA's Ability. (Op. cit., note 6, p. 53.)

[26] Ibid., pp. 47-48.

5. Congress Should Give FDA Authority to Detain Domestic Food Shipments Pending Analysis and to Impose Civil Penalties for Violations of Pesticide Tolerances.

FDA should be given greater authority to control interstate marketing of food that contains illegal residues. This should include the right to initiate civil penalties against violators of the food safety laws, and the right to detain food suspected of containing residues pending results of laboratory analyses.

Currently, FDA can only initiate criminal penalties against violators of the Federal Food, Drug and Cosmetic Act. The severity of criminal sanctions and the stringent burden of proof necessitated by such sanctions requires the FDA to expend considerable resources to support the charges. Consequently, FDA rarely takes legal action against violators. In the majority of cases an appropriate sanction would be significant civil penalties imposed against firms or individuals producing or shipping food with illegal residues in interstate commerce. FDA must have authority to impose such penalties.

FDA also needs explicit authority to detain domestic food shipments suspected of containing illegal residues until the analytical results have been obtained.[27] Without this authority, FDA frequently cannot prevent human dietary exposure to unsafe pesticide residues. If suspect shipments cannot be detained, the contaminated food may already have been consumed before final laboratory results are available.

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[27] FDA now only has the authority to detain imported food, pending results of its analysis for pesticide residues.

6. FDA's Pesticide Monitoring Resources Must Be Enhanced.

FDA's monitoring program has suffered from substantial staff cuts during the Reagan Administration. In 1980, FDA allocated about $12.7 million and 344 staff years to monitoring for pesticides. In 1985, despite the greater dimensions of the problem, pesticide monitoring consumed $13.7 million and only 309 staff years.[28] Resources available to the FDA's pesticide monitoring program need to be increased.

7. FDA Should Require Food Retailers to Label Fresh Produce With the Country of Origin. Interested Consumers Should be Able to Obtain Information on the Pesticides Used on Any Commodity Offered For Sale.

It is impossible for consumers to take action to limit their exposures to pesticides unless they can find out what pesticides were used in growing and storing the fruits and vegetables in their grocery stores. Consumers have a right to know about the pesticides used on foods they purchase. Grocery store managers should have information about the pesticides used in growing, storing and transporting the produce offered for sale. Food retailers could now require produce suppliers to provide information on pesticide use. Moreover, current federal law requires that pesticides applied to produce after harvest be identified on the shipping container. Concerned citizens should be able to review such information.

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[28] GAO, Pesticides: Need to Enhance FDA's Ability. (Op. cit., note 6, p. 12-13.)

The Federal Food, Drug and Cosmetic Act should be amended to include a provision giving consumers an explicit "right-to-know" about pesticides residues in food. Under such a provision, FDA should be required to obtain data on pesticide usage on food crops and make this information available to the public on request. Food retailers should also be required to disclose information about pesticide use and the country of origin of the produce they sell.

Because uses of many pesticides which are illegal in the United States occur in other countries, consumers should be informed when they are purchasing produce from abroad. FDA statistics indicate that imported fruits and vegetables have a consistently higher rate of violation of the U.S. pesticide laws. In fact, between 1979 and 1985, the pesticide residue violation rate for domestically-grown commodities averaged 2.9% whereas the violation rate for imported commodities averaged 6.1%.[29] If this trend continues, consumers may expect imported fresh produce to be twice as likely to violate the pesticide laws as domestic fruits and vegetables. FDA should require country-of-origin labelling so that consumers can immediately identify imported fruits and vegetables, which have become an increasingly large segment of the produce consumed in the U.S.

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[29] GAO, Pesticides: Need to Enhance FDA's Ability. (Op. cit., note 6, p. 25); and GAO, Pesticides: Better Sampling and Enforcement Needed on Imported Food, September 1986, p. 23.

C. Congress Must Act to Assist Growers in Reducing Pesticide Residues.

In addition to more effective EPA and FDA programs to regulate pesticides, the food supply will be best protected if growers have incentives to reduce their use of pesticides. Many farmers are willing to consider techniques that decrease pesticide applications, but barriers exist to the adoption of these methods.

Six basic reforms in federal farm policy, at minimum, are necessary to encourage growers to reduce pesticide use.

1. Congress Should Provide Credit Assistance, Crop Insurance, and Other Financial Protection for Growers Who are Changing From Conventional, High-Chemical Agriculture to Innovative, Low-Residue Techniques.

Most farmers know pesticides are costly and dangerous. Nevertheless, many growers are reluctant to modify their farming practices because of the financial risks involved. Alternative techniques such as integrated pest management (IPM) and organic farming can be used to greatly reduce or even eliminate pesticide residues in many crops. Instead of routinely spraying fields with herbicides, insecticides, and fungicides, IPM growers monitor their fields for pest infestations and use control measures only when they determine that the pests have reached an economically damaging level. IPM and organic growers both rely on a variety of techniques to limit pest infestation, many of which do not entail the use of any synthetic chemicals. Generally, organic growers apply no synthetic pesticides. IPM

growers may use some synthetic pesticides, but minimize use of chemicals they believe will disrupt the ecological balance of crop, pest and pest predators in their fields.

Although organic farming may ultimately prove profitable for many growers, there may be significant losses during the transition period in which the farmer learns and perfects the new techniques. Particularly for smaller growers who may not be able to survive several hard years, the disincentives to innovate are great.

Congress should assist growers who wish to modify their farming practices in ways that could greatly reduce pesticide use by offering them financial support. Credit assistance, crop insurance and other financial incentives should be provided for growers in transition between conventional farming and innovative, low-pesticide methods.

2. Congress Should Impose a Tax on Pesticides to Fund Demonstration of Farming Techniques That Will Result in Lower Pesticide Residues.

The development of alternative farming techniques to reduce pest problems, while reducing dependence on pesticides, requires research and field demonstration. In 1988, less than $4 million out of USDA's $1 billion annual research budget went toward the Department's new low-input ("sustainable agriculture") research program.

This valuable program and closely related endeavors should be greatly expanded. A tax as small as one percent on pesticide

products could raise tens of millions of dollars in revenue. Congress should direct these funds to experiments demonstrating techniques that can reduce farmers' reliance on pesticides and thus limit pesticide residues in food. The 1990 Farm Bill provides an excellent opportunity for Congress to enhance research in IPM and organic growing techniques, funded in part by a tax on pesticide products.

3. Congress Should Establish National Definitions of "Integrated Pest Management" and "Organic" Farming Techniques and Should Establish a National Certification Process for Commodities Grown Using These Techniques.

Consumers wishing to limit pesticide exposures may prefer to purchase products with minimized residues, grown using IPM or organic farming practices. However, not all states have defined "organic" farming. Those states that have are not always in agreement about the criteria which should apply. In the interest of consumer protection, there should be a national definition of "IPM" and "organic" farming. There also must be a national certification process to ensure that produce identified as "IPM-grown" or "organic" is truly in compliance with the national definitions. Only if Congress adopts such a system will consumers know that purchasing fruits or vegetables certified as "IPM-grown" or "organic" are getting what they pay for.

4. Congress Should Modify Federal Farm Support Programs to Ensure That Growers are Permitted and Encouraged to Use Crop Rotation and Other Pesticide-Reducing Techniques Without Jeopardizing Their Income.

Crop rotation can greatly reduce pest problems, particularly from soil-dwelling pests. However, many growers who qualify for support payments under the current federal commodity programs risk losing their eligibility, and hence their income, if they adopt crop rotation. This anomaly of the law must be changed. Congress should ensure that growers do not jeopardize their farm program eligibility by employing prudent, pesticide-reducing farming practices, including rotation of annual crops.

5. Congress Should Ensure That Crop Insurance Policies Do Not Discriminate Against Growers Using Organic or Integrated Pest Management Farming Practices.

Some growers have reported that crop insurance is not available unless they promise to rely on pesticides. The practice of some lenders of making crop insurance available only to conventional growers who apply pesticides intensively creates a dilemma for growers who wish to develop alternative farm practices that could decrease pesticide residues in food. Growers should not be penalized for their innovations in reducing pesticide residues. Congress should ensure that federal crop insurance policies do not discriminate against IPM or organic growers.

6. Congress Should Legislatively Modify Agricultural Supply-Control Systems to Ensure That They Do Not Enhance Demand for Cosmetically Perfect Produce Which Require Excessive Pesticide Use.

Currently, marketing and grading standards are developed by the agricultural industry to regulate the quantity of produce

offered for sale in this country. Such standards normally require commercial fruit and vegetables to meet very detailed color, size, shape and texture criteria. Fruit or vegetables which may meet these rigorous cosmetic standards may be neither the best tasting nor the most nutritious produce. Supply-control systems should reward nutritionally exceptional produce, not produce whose "perfect" appearance is achievable only by reliance on pesticides. Consumers should be informed that uniform color or size is not ordinarily correlated with nutrition or taste. Consumers should also know that much pesticide use is to improve the appearance of fruits and vegetables, not to improve taste or nutrition. Congress must modify the supply-control system to ensure that growers are rewarded for food which is good to eat, thereby lessening incentives for growing good-looking but pesticide-laden food.

NRDC thanks the Committee for your concern about the risks posed by pesticides in children's food. We hope to work closely with you to improve the safety of the nation's food supply by reducing pesticide use in agriculture. We'll be happy to answer any questions.

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